May 4, 2020

Case # 575990

VIA ELECTRONIC MAIL

Joseph S. Corgan
Co-Owner and Pharmacist In-Charge
Home Care Pharmacy of Palm Coast, Inc.
6 Florida Park Drive N., Suite A
Palm Coast, Florida 32137
homecarejc@aol.com

Mr. Corgan:

From April 23, 2018, to April 25, 2018 a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Home Care Pharmacy of Palm Coast, Inc., located at 6 Florida Park Drive N., Suite A, Palm Coast, Florida 32137. During the inspection, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on April 25, 2018. FDA acknowledges receipt of your facility's responses, dated May 8, 2018, September 25, 2018, and March 27, 2019, as well as your subsequent correspondence. We also acknowledge that your firm's voluntarily relinquishment of its sterile compounding license in the state of Florida was approved on February 26, 2018.

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 FDA approval prior to

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marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator 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 investigator noted that your firm handled hazardous drug products without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent contamination. In addition, your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483 as well as your subsequent correspondence. Regarding your response dated March 27, 2019, we acknowledge that our investigator observed the prescription for Rx (b)(6) in your Rx log, rather than observing the production.

Regarding your responses related to the insanitary conditions, 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. In your response dated September 25, 2018, you state deactivating, decontaminating, cleaning (using germicidal detergent and water), and disinfection with (b) (4) of your Biosafety Cabinet (BSC) occurs at the (b) (4) of use. In addition, you state that decontamination of the BSC occurs (b) (4) and (b) (4) (b) (4) compounding, when spills occur, and when contamination is known to be present. However, you did not provide the referenced standard operating procedure for our review.

   In addition, we acknowledge that both (b) (4) and water are known decontamination agents. However, a decontamination step with water and/or (b) (4) may only remove some drug residue, leaving behind residue that may not be deactivated. From your responses, it is not clear if a deactivation agent (e.g., oxidizing agent) is applied to your non-dedicated work surface after each batch

[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.

preparation of hazardous, sensitizing, or highly potent drug products including, but not limited to, hormones and beta-lactam products. Therefore, we remain concerned that hazardous, sensitizing, or highly potent drug product residue that is not rendered inert or inactive by a deactivation agent, may be introduced into subsequent products produced in your non-dedicated work area.

2. In your response dated September 25, 2018, you state that utensils and used lab equipment are soaked in a basin of water (b) (4) solution and then washed thoroughly. However, you did not provide supporting documentation for our review, such as the formulation records for the water (b) (4) solution, applicable standard operating procedures, and training records.

3. In your response dated September 25, 2018, you state that the (b) (4) water used in your compounding formulations is "pharmaceutical grade" water and that the label states it is prepared by (b) (4) from a (b) (4) and tested (b) (4) source. We acknowledge that water may be (b) (4) However, you have not demonstrated that the (b) (4) water you are using in non-sterile production is meeting, at minimum, the *Purified Water*, USP monograph.[2] If you continue to use (b) (4) water in non-sterile drug preparations, we recommend you provide tests results or other documentation to demonstrate that the water is meeting, at minimum, *Purified Water*, USP. In addition, water used in production should be under microbiological control (e.g., no more than 100 CFU/mL; see inspection guide – https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/high-purity-water-system-793). Alternatively, bulk or packaged forms of water that indicate on the label that the water is, at minimum, *Purified Water*, USP could be used.

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 [21 U.S.C. § 353a].

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 violations. Please include an

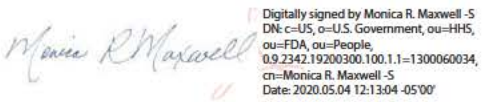
[2] USP Chapter <795> (Pharmaceutical Compounding – Non-Sterile Preparations) states that "*Purified Water* (see *Purified Water* monograph) shall be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water."

explanation of each step being taken to prevent the recurrence of 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 30 working days, state the reason for the delay and the time within which you will complete the correction.

Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, M.S., Director, Compliance Branch, at orapharm2_responses@fda.hhs.gov. Any written correspondence should refer to case #575990.

If you have questions regarding the contents of this letter, you may contact Mr. Thao Ta, Compliance Officer, via phone at 214-253-5217 or e-mail at thao.ta@fda.hhs.gov.

Sincerely,



Monica R. Maxwell
Program Division Director
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