U.S. Food and Drug Administration
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

EMAIL DELIVERY
RETURN RECEIPT REQUESTED

March 18, 2021

Jeffrey H. Liebman
Chief Executive Officer
CharterCare Health Partners
825 Chalkstone Avenue
Providence, RI 02908-4728

Dear Mr. Liebman:

From July 22, 2019, to August 14, 2019, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Roger Williams Medical Center Oncology Pharmacy Clinic, located at 50 Maude Street, Providence, Rhode Island 02908. During the inspection, the investigators noted deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on August 14, 2019. FDA acknowledges receipt of your facility's response, dated September 5, 2019. 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 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

[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.

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

1. Your facility design may allow the influx of poor-quality air into a higher classified area. Specifically, your firm utilizes (b) (4) unclassified (b) (4) that connect an unclassified space directly to ISO 7 classified areas in which aseptic processing is performed. In addition, your firm did not ensure that air pressure differentials were maintained between classified areas, in that pressure gauges were either broken or absent.

2. A non-sterile disinfecting agent, non-sterile (b) (4) and non-sterile cleaning pads were used in the ISO 5 classified aseptic processing areas.

3. Microbial contamination was present in areas adjacent to the ISO 5 areas during aseptic production without adequate remedial action.

4. The ISO-classified areas had difficult to clean and particle-generating equipment.

5. Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

6. The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

7. Your facility was designed and operated in a way that permits poor flow of personnel. Specifically, personnel must (b) (4) the ISO 7 Chemo Room, where hazardous drugs are produced, in order to enter the ISO 7 Clean Room, where non-hazardous drugs are produced.

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, the following corrective actions appear inadequate :

1. Regarding the (b) (4), we acknowledge your testing results and statement that the work areas directly to the exterior of the (b) (4) have been cleaned and non-essential items relocated to other areas. However, we remain concerned that your firm continues to use the (b) (4), as they may allow unclassified air to compromise the air quality in the ISO 7 rooms surrounding the ISO 5 aseptic processing areas. This is of particular concern for your (b) (4), which is designed to (b) (4).

2. Your firm continues to use non-sterile (b) (4) to disinfect your ISO 5 aseptic processing areas. The use of a non-sterile disinfectant increases the risk of contamination in the aseptic processing area.

In addition, regarding the flow of personnel within your facility, you stated in your response, "Director of Facilities has reviewed this location with an architect and engineer in order to determine best alternative workflow patterns for this area. Further review is scheduled for (b) (4) . If no solution is identified by (b) (4) You also stated, "(b) (4) " Please provide a status update on these commitments.

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 processing expertise should assist you in conducting this comprehensive evaluation.

For more information on compounding, please see FDA's website, at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

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. 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 any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related supporting 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 address your reply to LCDR Nancy Scheraga, OPQO Division I Compliance Officer, at ORAPHARM1_RESPONSES@fda.hhs.gov. If you have questions regarding the contents of this letter, please contact Nancy Scheraga at 973-331-4910 or by email at nancy.scheraga@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300011579, cn=Diana Amador-toro -S
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Diana Amador-Toro
Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I