August 21, 2020

Case #: 609986

VIA ELECTRONIC MAIL

Kevin J. McClung, D.Ph.
Owner and Pharmacist in Charge
Vital Care of Dickson, LLC
758 Hwy 46 South, Suite 100
Dickson, Tennessee 37055
(b) (6)

Dr. McClung:

From March 4, 2020, to March 11, 2020, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Vital Care of Dickson, LLC, located at 758 Hwy 46 South, Suite 100, Dickson, Tennessee 37055. During the inspection, the investigator 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 March 11, 2020. FDA acknowledges receipt of your facility's response, dated March 31, 2020. 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] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

Specific violations are described below.

[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.

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator 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 [21 U.S.C. § 351(a)(2)(A)]. For example, the investigator observed that your firm has not conducted media fills which simulate the most complex and timely manipulations routinely performed during aseptic operations. Your firm does not routinely monitor pressure differentials between areas with differing air classifications before or during aseptic operations; differential pressure manometers are not visible to operators during aseptic operations. Additionally, your facility is not designed to prevent insanitary conditions and you use a non-sterile disinfectant within your ISO 5 processing area.

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 response 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. You identified Total Parenteral Nutrition (TPN) products as being representative of the most complex and timely aseptic operations at your firm and provided a newly generated procedure and a record of employee training. However, you did not provide evidence of the procedure being representative of actual TPN production, including the number and type of manual manipulations, specific equipment used, nor length of operations. Regarding the executed media fills, you did not provide documentation to demonstrate which operators performed media fills per this new procedure nor the results of those media fills.

2. Regarding deficient pressure differential monitoring, you stated that you took, "interim steps to address these issues by conducting a performance improvement meeting at which all staff were instructed that gradient pressure must be monitored and recorded on a daily basis." However, you did not provide details of how and when gradient pressure will be documented, who is responsible for documenting gradient pressure, nor evidence that interim daily monitoring has been performed since this meeting occurred on March 12, 2020.

Additionally, you provided a quote from (b) (4) for a continuous pressure differential monitoring system. However, you did not provide evidence of its purchase, installation, and operation.

3. During the inspection, your anteroom and cleanroom were observed to have non-sealed air gaps around light fixtures in the ceiling. However, you have not provided any evidence to demonstrate the air gaps have been appropriately repaired.

4. You indicated you would change from non-sterile (b) (4) to pre-sterilized (b) (4) for use in your aseptic processing areas. You stated the (b) (4) disinfectant would become available in mid-April, but have yet to provide evidence of its purchase and an updated cleaning procedure.

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 violations. Please include an 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 thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please electronically submit your reply on company letterhead to CDR John W. Diehl, MS, Director, Compliance Branch, at orapharm2_responses@fda.hhs.gov and Samantha.Bradley@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Samantha Bradley, Compliance Officer, via phone at (205) 731-0017 ext. 1004 or email at Samantha.Bradley@fda.hhs.gov.

Sincerely,

Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations, Division II