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

March 18, 2019

Case # 544211

VIA UPS EXPRESS

Patricia Stephens
Owner and President
Medi-Fare Drug & Home Health Center, Inc.
300 W. Pine Street
Blacksburg, South Carolina 29702-1548

Ms. Stephens:

You registered with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on December 14, 2017. From March 15, 2017, to April 6, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Medi-Fare Drug & Home Health Center, Inc., located at 300 W. Pine Street, Blacksburg, South Carolina 29702-1548.

Following the inspection, FDA requested additional information from your firm on August 24, 2017. FDA acknowledges receipt of your firm's response, dated October 2, 2017. Information collected during the inspection and submitted in response to our August 24, 2017 request revealed serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

Based on this inspection, it appears your firm produced drugs that violate the FDCA.

A. Violations of the FDCA

Adulterated Drug Products

Our review of the establishment inspection report (EIR) and your responses to our written request for additional information identified CGMP violations at your facility that caused your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example, that your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions (21 CFR 211.42(c)(10)(v)).

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[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

B. Corrective Actions

In your response to our request for additional information dated October 2, 2017, you described certain corrective actions. However, we still have the following concerns:

1. In response to the inadequate cleaning issue, your response included a copy of SOP # 4.020 "*Cleaning and Disinfecting of the Clean Room Facility*" which reads, in part "*.. (b) (4) is used per the cleaning SOP as a sporicidal. (b) (4) (b) (4) is the only agent listed with sporicidal properties. Medi-Fare's (b) (4) solution utilizes (b) (4) at (b) (4)*" However, the procedure includes the following references:

- *"Area Cleaning Requirements: .. (b) (4) change of cleaning agents it is recommended to do(b) (4) cleaning with a sporicidal agent."*

- *"Cleaning BSC's: .. (b) (4) (b) (4) , if the BSC is to be used (b) (4) (b) (4) ."*

- (b) (4) *Cleaning and Maintenance of Controlled Environments: …A sporicidal should be used at least (b) (4) for the entire manufacturing areas (i.e. prep room, gowning room, manufacturing room(b) (4) and visualization/labeling room."*

Your written procedures appear inadequate in that the use of a sporicidal agent is not explicitly required for cleaning of ISO-5 classified workstations at any prescribed frequency; instead, use of a sporicidal agent is merely recommended. You did not identify the actual (b) (4) product used and you did not describe the procedures for its mixing and dilution. Therefore, the actual concentration of (b) (4) remains unknown. Additionally, we are unable to evaluate the effectiveness of the [cleaning] solution as a sporicidal agent since your procedures do not specify a contact time for any of your cleaning agents. Lastly, you failed to provide cleaning logs or any other such documentation to verify the use of any cleaning agents, including sporicidal agents, in any specific locations, or frequency.

2. In addition, we remain concerned with your inability to demonstrate that your hoods provide adequate protection of the ISO-5 area. For example, your response failed to address the adequacy of any air pattern analyses (i.e. "smoke studies") conducted prior to August 29, 2017. Consequently, we remain concerned that sterile products produced prior to that date were prepared in an environment that poses a contamination risk. Also, your response failed to include a study protocol or report for the smoke studies conducted on August 29, 2017. Since the outcome of those tests is unknown we are unable to evaluate the suitability of the ISO-5 classified environment for sterile drug production activities.

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

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 if you have taken any steps 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 30 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Case # 544211. Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, M.S., Director, Compliance Branch, at john.diehl@fda.hhs.gov, mark.rivero@fda.hhs.gov, and orapharm2_responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Mark Rivero via phone at 504-846-6103 or via email at mark.rivero@fda.hhs.gov.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
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for

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