Stanley Specialty Pharmacy Compounding and Wellness Center 7/24/18

Office of Pharmaceutical Quality
Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

July 24, 2018

CMS Case # 557711

WARNING LETTER

VIA UPS EXPRESS

Douglas Yoch, Pharmacist-in-Charge
Stanley Specialty Pharmacy Compounding and Wellness Center
3120 Latrobe Drive, Suite 200
Charlotte, North Carolina 28211-2185

Dear Mr. Yoch:

From July 31, 2017 to August 4, 2017, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Stanley Specialty Pharmacy Compounding and Wellness Center, located at 3120 Latrobe Drive, Suite 200, Charlotte, North Carolina 28211-2185. An FDA investigator previously inspected this facility from June 6, 2016 to July 7, 2016. During both the 2016 and 2017 inspections, the investigators noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on July 7, 2016, and again on August 4, 2017. FDA acknowledges receipt of your facility's responses, dated August 21, 2016, and August 22, 2017. FDA also acknowledges receipt of your facility's response, dated March 22, 2017, to FDA's letter, dated March 16, 2017. These responses outlined the corrections you planned to take to address the inspectional findings.

Based on these inspections, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA Adulterated Drug Products

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. Non-sterile wipes and non-sterile cleaning agents are used in the ISO 5 classified aseptic processing areas.

2. Surface sampling of the ISO 5 classified aseptic processing areas is not always conducted before cleaning occurs.

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.

Corrective Actions

We have reviewed your firm's response dated August 22, 2017, March 22, 2017, and August 21, 2016, to address the inspectional findings.

Regarding other observations cited in the 2017 Form FDA 483, your corrective actions appear deficient as described below:

1. Your disinfection practices pose a risk to the sterile drug products produced as the use of sterile 70% IPA wipes following the use of non-sterile wipes and non-sterile cleaning agent within your aseptic processing areas will not kill the spores present in the non- sterile wipes and cleaning agent. Further, the use of non-sterile wipes and cleaning agent have the potential to introduce contamination into the ISO 5 hoods. Moreover, the use of non-sterile wipes to apply and remove the sporicidal agent also has the potential to spread spore contamination.

2. Conducting surface sampling after the aseptic processing areas have been cleaned may not allow your firm to identify potential routes of contamination within your aseptic processing environment.

In addition, FDA conducted a thorough review of the documentation collected during our inspections of your facility and found additional deficiencies with some of your practices and procedures that were not listed on the Form FDA 483 issued to your firm at the conclusion of our inspections. Specifically, your firm compounds some drug products that are intended to be sterile from multi-use bulk stock solutions that have been sterile filtered. However, you do not conduct an additional sterilization step before filling the finished sterile drug product into the individual dosage form (container). This includes your preparation of bulk solutions of finished sterile drug products. This practice poses a risk to patients as the stock solution is exposed to lower than ISO 5 quality air during storage that could compromise drug sterility.

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].

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.

B. 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.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) 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 15 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 Warning Letter Number above (CMS Case #557711). Please address your reply to John W. Diehl, Director, Compliance Branch, at the FDA address provided on bottom of first page of this letter. Additionally, please submit a signed copy of your response on your firm's letterhead to ORAPHARM2_Responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.asente@fda.hhs.gov.

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

Cc:
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