Home Care Pharmacy of Palm Coast, Inc. 8/31/17

U.S. FOOD & DRUG ADMINISTRATION

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

August 31, 2017
CMS Case # 524658

WARNING LETTER

VIA UPS EXPRESS
Joseph S. Corgan, Pharmacist-In-Charge and President
Home Care Pharmacy of Palm Coast, Inc.
6 Florida Park Drive North, Suite A
Palm Coast, Florida 32137
Dear Mr. Corgan:

From May 17, 2016, to May 25, 2016, 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 North, Palm Coast, Florida 32137. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. In addition, the investigator 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 May 25, 2016. FDA acknowledges receipt of your facility's response, dated June 12, 2016. Based on this inspection, it appears that you produced drug products that violate the 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 practices (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.

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigator noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigator

noted that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.
Therefore, you compounded drug products (collectively the “ineligible drug products”) that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA.
Specific violations are described below.

C. 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 found that during the cleaning of the ISO 5 area, your firm used a **(b)(4)**, did not use a sporicidal agent, and lacked established contact times for adequate disinfection. Also, a technician was observed wearing nonsterile gloves and using **(b)(4)** container in the ISO 8 area. Furthermore, your ISO 8 area does not have HEPA filters in the ceiling air supply vents where the ISO 5 **(b)(4)** is located.
Furthermore, the manufacture of the ineligible drug products is subject to FDA’s CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigator observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA.
The violations included, for example:
1) Your firm failed to establish and follow an adequate system for cleaning and disinfecting the room and equipment used to control the aseptic conditions (21 CFR 211.42(c)(10)(v)).
2) Your firm failed to ensure the air supply was filtered through high-efficiency particulate air filters under positive pressure in your aseptic processing area (21 CFR 211.42(c)(10)(iii)).
3) Your firm failed to establish and follow an adequate system for monitoring environmental conditions (21 CFR 211.42(c)(10)(iv)).
4) Your firm failed to ensure each batch of drug product purporting to be sterile and pyrogen-free was laboratory tested to determine conformance to such requirements (21 CFR 211.167(a)).
5) Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).
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 any human or animal 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.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical

practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses, and they are not exempt from the requirements of section 502(f)(1) of the FDCA (see, e.g., 21 CFR 201.115). Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. It is a prohibited act under section 301(k) of the FDCA 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 misbranded.

D. Corrective Actions

We have reviewed your firm's responses to the Form FDA 483. Some of the proposed corrective actions described in your response do not adequately correct the insanitary conditions noted at your facility. For example:

1. In your response to the observation regarding the use of non-sterile wipes in the aseptic processing area, you stated that USP <797> suggests using low shedding and non-shedding wipes, but does not specify that such wipes must be sterile. However, non-sterile wipes increase the potential for contamination to be introduced into the aseptic processing area as well as the product, and therefore should not be used. We are unable to determine from your response if you have implemented the use of sterile wipes in your cleanrooms.
2. Your response did not provide documentation to support the concentration and required contact time of your cleaning agents to ensure that adequate disinfection and spore killing activity occurs in the aseptic processing area.
3. In your response to the observation regarding the lack of HEPA filters in your ISO 8 room, you stated that USP <797> does not require HEPA filtered air in an ISO 8 room and the only requirement is a particle count less than 3,520,000/m3. However, in order to properly maintain the appropriate particulate classification of an area, your facility will have to be designed and controlled to ensure the environmental quality, including HEPA filtration air entering the cleanroom to remove particles, is maintained at all times.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether the drugs are compounded and distributed after receipt of a valid prescription for an identified-individual patient.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations. ***2***

FDA strongly recommends that your management undertake a comprehensive assessment of 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.

E. 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 fifteen (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 Unique CMS Identification Number: 524658.
Please address your reply to John W. Diehl, Acting Director, Compliance Branch, at the FDA address provided on the first page of this letter. In addition, please submit a signed copy of your response to john.diehl@fda.hhs.gov.
If you have questions regarding the contents of this letter, please contact John W. Diehl at (214) 253-5288.

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

Cc: Christopher Ferguson, Chief
Florida Department of Health
Investigative Services Unit
4052 Bald Cypress Way, Bin C-70
Tallahassee, Florida 32399

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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.
2 In this letter we do not address whether your proposed corrective actions would resolve the CGMP violations noted above.