Medical Center Pharmacy, Inc. 7/21/17

U.S. FOOD & DRUG ADMINISTRATION

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

July 21, 2017

CMS Case # 517544

WARNING LETTER

VIA UPS EXPRESS

Joseph S. Moore, Owner
Medical Center Pharmacy, Inc.
2401 North Ocoee Street.
Cleveland, Tennessee 37311-3853

Dear Mr. Moore:

From September 28, 2015, to October 13, 2015, U.S. Food and Drug Administration (FDA) investigators inspected your facility located at 2401 North Ocoee Street, Cleveland, Tennessee, 37311-3853. During the inspection, the investigators 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. 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 facility on October 13, 2015. FDA acknowledges receipt of your facility's responses, dated October 15, 2015, and December 2015 (received on January 4, 2016). Based on this inspection, it appears that you produced drugs that violate the FDCA.

A. Compounded Drugs 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 of the FDCA.

B. Failure to Meet the Conditions of Section 503A

During the inspection, FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A of the FDCA. For example, the investigators noted your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, your firm 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 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 [21 U.S.C. § 351(a)(2)(A)]. For example, investigators observed **(b)(4)** on laminar flow hood (LFH) countertops, which is a porous and difficult-to-clean surface. Investigators also observed that your firm failed to use **(b)(4)** or a **(b)(4)** as part of the **(b)(4)** for the ISO 5 laminar hoods and ISO 7 cleanroom, where sterile drug products are prepared. Your firm failed to document and demonstrate, through appropriate studies, that your hoods are able to provide adequate protection of the ISO 5 area in which sterile products are being produced. Lastly, investigators observed exposed skin on the lower extremities, face, and neck of cleanroom operators after gowning.

Furthermore, the manufacture of these ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigators 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 an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions [21CFR 211.42(c)(10)(v)].
2. 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)].

3. Your firm failed to establish an adequate system for monitoring environmental conditions in the aseptic processing area [21 CFR 211.42(c)(10)(iv)].
4. Your firm does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product [21 CFR 211.167(a)].
5. Your firm failed to adequately design the facility with adequate separation or defined areas or such other control systems necessary to prevent contamination or mix-ups [21 CFR 211.42(b)].
6. Your firm failed to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed [21 CFR 211.192].
7. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug product from contamination [21 CFR 211.28(a)].

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.

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 October 15, 2015 and December 2015 (received on January 4, 2016) responses to the Form FDA 483. Although some of your corrective actions regarding insanitary conditions appear adequate, others are inadequate. Your firm states that you operate as a “compounding pharmacy” and in compliance to USP <797>, and therefore you did not implement changes to correct certain insanitary conditions claiming they are not required by USP<797>. For example, it appears your firm will not be implementing the use of **(b)(4)** or **(b)(4)** disinfectants as part of your cleaning and disinfecting procedures.

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, including the condition for receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

In addition, regarding observations related to the conditions of section 503A of the FDCA, your firm states that it “only compounds prescriptions which are for individually identified patients pursuant to a valid prescription from a provider.” However, FDA investigators obtained evidence of non-patient-specific prescriptions. Should you continue to compound and distribute drug products that do

not meet the conditions of section 503A of the FDCA, 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 sections 505 and 502(f)(1) of the FDCA and fully implement corrections that meet the minimum requirements of the CGMP regulations.

FDA strongly recommends that your management first undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess 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 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 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 # 517544**).

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:

Mr. Reginald Diller, Executive Director
Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, Tennessee 37243

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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.