W & C dba The Apothecary 7/20/17

U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical
Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393 -8100
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July 20, 2017
WARNING LETTER
Case# 508183

UPS NEXT DAY
SIGNATURE REQUIRED

Mr. Stephen G. Anderson, R.Ph.
Owner and Pharmacy Manager
W & C Apothecary, dba The Apothecary
165 19th Street South, Suite 102
Sartell, MN 56377-2567

Dear Mr. Anderson:

From June 6, 2016, to June 17, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, W & C Apothecary dba The Apothecary, located at 165 19th Street South, Suite 102 Sartell, MN 56377-2567. 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. In addition, 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 June 17, 2016. FDA acknowledges receipt of your facility's response, dated June 30, 2016, in which you stated: "Please accept this as notification that as of June 17, 2016, W & C Apothecary will cease and desist compounding of any and all sterile prescription products." FDA also acknowledges your firm's June 17, 2016 commitment to investigators to voluntarily recall your entire line of drug products intended to be sterile within expiry. 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, FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. 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, 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 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 noted that your firm continued operation in the ISO 7 “Anteroom **(b)(4)**” after its HEPA filter failed to pass certification due to unrepairable leaks. Your firm failed to use sterile wipes and used a non-sterile disinfectant as part of your disinfection program for the aseptic processing area. In addition, your firm did not use a sporicidal agent in the Laminar Flow Hood (LFH) where sterile drug products were prepared; nor did your firm use an adequate contact time for the sporicidal agent used to disinfect the ISO 7 and ISO 8 areas. Furthermore, the investigators found that your firm failed to demonstrate, through appropriate studies, that your LFH was able to provide adequate protection of the ISO 5 area, where sterile products were produced.

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 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 maintaining equipment used to control the aseptic conditions (21 CFR 211.42(c) (10)(vi)).

2. 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)).

3. 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)).

4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

5. Your firm failed to reject drug products that did not meet established standards or specifications and any other relevant quality control criteria (21 CFR 211.165(f)).

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 firm's response to the Form FDA 483. We acknowledge your June 17, 2016 action to cease compounding of any and all sterile drug products and voluntarily recall all sterile products within expiry.

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 receipt of a prescription for an identified individual patient prior to compounding and distributing drug products. If you decide to resume operations, you must correct all insanitary conditions at your firm.

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.

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first 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.

If you decide to resume sterile operations, 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 if you have taken any specific steps to correct the violations cited in this letter, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, 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 violated the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office 15 days prior to resuming production of any sterile drugs in the future.

Please address your reply to:

Brian D. Garthwaite, Ph.D., Compliance Officer
U. S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
Minneapolis Office
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401-2142

Refer to the Unique Identification Number (Case# 508183) when replying. If you have questions regarding the contents of this letter, please contact Dr. Brian Garthwaite by phone at (612) 758-7132 or by email at Brian.Garthwaite@fda.hhs.gov.

Sincerely,
/S/
Art O. Czabaniuk
Division Director
Division of Pharmaceutical Operations III

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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.