U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPOO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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December 9, 2019

VIA UPS NEXT DAY
SIGNATURE REQUIRED

Tony L. Jones
President/Pharmacist-in-Charge
John's Pharmacy Inc. dba The Sullivan Pharmacy
102 East Harrison Street
Sullivan, IL 61951-2002

Ref: Case 257455

Dear Mr. Jones,

From February 12, 2019, to February 22, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, John's Pharmacy Inc. dba The Sullivan Pharmacy, located at 102 East Harrison Street, Sullivan, IL 61951. 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 deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on February 22, 2019. FDA acknowledges receipt of your facility's response, dated March 8, 2019. Based on this inspection, it appears that you produced drugs 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 practice (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.

[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.

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 and distributed, including lidocaine/tetracaine/phenylephrine gel and lidocaine/tetracaine/epinephrine gel.

Therefore, you compounded 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. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products."

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products 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 investigator observed that:

1. Your firm failed to confirm that the quality of water was suitable for its intended use in the production of non-sterile drug products.

2. Hazardous drugs were produced without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.

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, your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(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.[2] 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 [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 misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding the insanitary condition observations in the Form FDA 483, some of your corrective actions appear to be adequate. However, we cannot fully evaluate the adequacy of the following corrective action described in your response because you did not include sufficient information or supporting documentation:

Your response indicated that your firm is purchasing (b) (4) (b) (4) for use in non-sterile drug production until your (b) (4) unit would be serviced in June 2019. However, you did not provide an updated copy of your referenced procedures or any updates on the testing performed by your vendor in June 2019.

Regarding observations related to the conditions of section 503A of the FDCA, as explained above, receipt of valid prescriptions for individually-identified patients is a condition of section 503A, which your firm failed to meet for a portion of the drug products you produced.

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].

Should you 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 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.[3]

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[2] Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

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

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. See section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you introduce into interstate commerce are neither adulterated nor misbranded. [See 21 CFR 210.1(b), 21 CFR 200.10(b)].

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.

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 remaining concerns. 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 the corrective actions within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please send your electronic reply to:

ORAPHARM3_RESPONSES@fda.hhs.gov
Attn: Russell K. Riley, Compliance Officer
Division of Pharmaceutical Quality Operations III
U. S. Food and Drug Administration

In your reply please reference "Case 257455".

If you have questions regarding the contents of this letter, please contact Russell K. Riley, Compliance Officer at 630-323-2763 x. 101 or at ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2019.12.10 14:49:07 -05'00'

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations 3
U.S. Food and Drug Administration