FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA SIGNATURE CONFIRMED DELIVERY

August 18, 2020

Allan Jolly, R.Ph., Owner
Infusion Treatment Center Inc.
dba ITC Compounding and Natural Wellness Pharmacy
651 Topeka Way, Suite 600
Castle Rock, CO 80109-3116

Dear Mr. Jolly:

From July 12, 2019 to July 23, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Infusion Treatment Center Inc. dba ITC Compounding and Natural Wellness Pharmacy, located at 651 Topeka Way, Suite 600, Castle Rock, CO. 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.

FDA issued a Form FDA 483 to your firm on July 23, 2019. FDA acknowledges receipt of your facility's response, dated August 8, 2019. FDA further acknowledges your written commitment to cease production and distribution of drug products for office stock, effective July 22, 2019.

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 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

[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.

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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 your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced. The non-patient specific prescriptions included, for example, Benzocaine/Lidocaine/Tetracaine 20%/8%/8% Transdermal and Tetracaine/Lidocaine/Prilocaine/Phenylephrine (Spearmint) 4%/10%/10%/2% Lipoderm. Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions in that section, including 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 non-sterile 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 your firm produced hazardous products as well as non-hazardous products with shared equipment, work surfaces, and utensils without adequate cleaning. Additionally, the investigator observed deteriorated equipment and utensils, and non-pharmaceutical grade water used in drug production.

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 have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).

2. Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

3. Your firm failed to establish and follow adequate written responsibilities and procedures applicable to the quality control unit (21 CFR 211.22(d)).

4. Your firm failed to provide current good manufacturing practices training to employees (21 CFR 211.25(a)).

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.

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 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 your response related to the insanitary conditions, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. Your response did not include supporting documentation, such as revised cleaning procedures for cleaning between the production of hormone and non-hormone products.

2. Your response did not include new (b) (4) procedures for thyroid products, including separation of products as well as cleaning of the (b) (4) .

[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).

In addition, some corrective actions appear deficient, for example, your response did not address interim control measures implemented for production of hazardous drugs.

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 on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

Regarding issues related to the conditions of section 503A of the FDCA, your corrective actions appear adequate, in that, we acknowledge your response stating "as of 7/22/2019 [you] will no longer be compounding for office use including human and veterinary compounds."

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.[3]

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 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 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 ORAPharm4_responses@fda.hhs.gov or mail your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Irvine, CA 92612-2506

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

Please identify your response with unique identifier 608379.

If you have questions regarding any issues in this letter, please contact CAPT Matthew R. Dionne, Compliance Officer via email at Matthew.Dionne@fda.hhs.gov or by phone at (303)-236-3064.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mrd