U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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September 18, 2023

UNTITLED LETTER

Case# 494233

UPS NEXT DAY
SIGNATURE REQUIRED

Fayez Faraj, Owner
SNF Holdings, LLC dba Vios Compounding
31035 Schoolcraft Road
Livonia, MI 48150-2029

Dear Mr. Faraj:

From February 13, 2023 to March 2, 2023, U.S. Food and Drug Administration (FDA) investigators inspected your facility, SNF Holdings, LLC dba Vios Compounding, located at 31035 Schoolcraft Road, Livonia, MI 48150. 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 deficiencies in your practices for producing non-sterile drug products.

FDA issued a Form FDA 483 to your firm on March 2, 2023. FDA acknowledges receipt of your facility's response, dated March 16, 2023. 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 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 investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced, including DMSO/Lidocaine/Prilocaine/Tetracaine 5/10/6/4% Cream and Benzocaine/Lidocaine/Tetracaine (BLT) 20/10/10% Cream.

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 investigators 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 investigators observed that:

1. You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

2. You used active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents, i.e., you used (b) (4) as a component in the formulation of a drug product.

3. Non-microbial contamination was observed in your production area.

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.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for the ineligible drug products that you compounded.[2] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. § 331(d)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

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.[3] Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. It is also 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(s) related to the insanitary conditions, some of your corrective actions appear adequate; however, 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:

> Regarding observations 1 and 3, you committed to perform a residue test on equipment (b) (4) using a third-party lab. However, you did not specify which equipment will be tested or how the equipment to be tested will be chosen. In addition, you did not provide a full assessment with an action plan to mitigate the potential for chemical cross contamination of your compounded drug products with the highly potent and widely varied drug substances handled in your compounding areas. Some examples of these drug substances include estradiol, levothyroxine T3 and T4, progesterone, dehydroepiandrosterone (DHEA), ivermectin, and ketamine.

You did not address certain observations related to insanitary conditions, for example:

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[2] The specific products made by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

[3] 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).

Regarding your response(s) related to the insanitary conditions, the following corrective actions appear deficient:

> Regarding observation 2, you began purchasing (b) (4) on or around 02/27/2023, after FDA investigators informed Mr. Fayez Faraj, Owner and PIC, that (b) (4) must be used to produce non-sterile drug products. However, you did not commit to establishing in-house specifications for microbial levels above which the (b) (4) you use to compound drug products is unsuitable for use. Your firm also failed to commit to ensuring the (b) (4) used meets USP limits for total fungal count. In addition, your firm failed to commit that the (b) (4) used to compound human drug products including nasal sprays is free from objectionable organisms such as *Escherichia coli*, *Salmonella*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.

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.

In addition, regarding issues related to the conditions of section 503A of the FDCA, we acknowledge your statement that "measures will be implemented to ensure that all compounds will only be released if they are for patient use only."

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.[4]

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 produce 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 any violations and for

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

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 address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

Your written notification should refer to the reference number (494233). Please electronically submit your reply on company letterhead to Brian Nicholson, Compliance Officer, at ORAPHARM3_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to brian.nicholson@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Brian Nicholson at 630-207-9337 or brian.nicholson@fda.hhs.gov.

Sincerely,

Jeffrey D. Meng -S
Digitally signed by Jeffrey D. Meng -S
Date: 2023.09.18 10:15:15 -04'00'

Jeffrey Meng
Program Division Director
Division of Pharmaceutical Quality Operations III