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

VIA SIGNATURE CONFIRMED DELIVERY

September 27, 2023

Shahram Soroudi
Owner
Palisades Compounding Pharmacy
540 Palisades Dr.
Pacific Palisades, CA 90272-2445

Dear Mr. Soroudi:

From February 23, 2023, to March 15, 2023, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Palisades Compounding Pharmacy, located at 540 Palisades Dr., Pacific Palisades, CA 90272. During the inspection, the investigator collected evidence indicating 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 non-sterile drug products.

The FDA issued a Form FDA 483 to your firm on March 15, 2023. The FDA acknowledges receipt of your facility's response, received on April 4, 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.

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigator collected evidence indicating that drug products produced by your firm failed to meet the conditions of section 503A. For

[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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19701 Fairchild Road, Irvine, CA 92612-2506
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example, the investigator collected evidence indicating that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced, including Salicylic Acid 30% Peel and Benzocaine/Lidocaine/Tetracaine 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 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:

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

2. Your firm distributed drug products that were prepared using expired components.

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

[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).

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 responses 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:

1. We acknowledge your response that you are now using a pharmaceutical grade detergent, "…we are now using one made by (b) (4) as our one and only detergent to clean our utensils." However, you did not provide the specific (b) (4) detergent used or the Material Safety Data Sheet (MSDS). In addition, you did not provide the cleaning procedure regarding utensils. Furthermore, you did not provide evidence that the proposed cleaning agent is capable of removing residual drug product in order to prevent cross-contamination.

2. We acknowledge your response that you "...are now using assigned (b) (4) blades for each chemical used.…Each blade will still get cleaned with detergent prior to being used again the next day, however they are now only being used for their assigned chemical." However, you did not provide updated procedures regarding the use/change of the (b) (4) blades and did not provide the updated cleaning procedures for the (b) (4) blades.

3. We acknowledge your response, "…our staff will use a completely new set of (b) (4) jars and (b) (4) blades, which also eliminates the change of any cross contamination." However, you did not provide updated procedures regarding the operation of the Unguator to include the usage of (b) (4) jars and (b) (4) blades. Provide the make/model and number of all Unguators used; directions of how the (b) (4) blades and (b) (4) jars are changed from the Unguator shaft; and provide evidence there is no product contact with Unguator shaft as the (b) (4) blades and (b) (4) jars are changed.

4. We acknowledge your response, "…the actual (b) (4) used had an expiration date of 05/16/2024 but during the typing of the formulation log sheet, it was typed in error." However, you did not provide supporting documentation such as: the lot number and Certificate of Analysis of the (b) (4) with expiration date: 05/16/2024 or the investigation including the corrective and preventative action resulting from this deviation.

5. We acknowledge your response, "…The actual date on the (b) (4) used was 11/23/2023." However, you did not provide supporting documentation such as: the lot number and Certificate of Analysis for the (b) (4) with expiration date:

11/23/2024 or the investigation including the corrective and preventative action resulting from this deviation.

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.

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.

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]

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 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.

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

Your written notification should refer to the CMS 668131. Please address your reply to ORAPHARM4_Responses@FDA.HHS.GOV with ATTN: CDR Steven E. Porter, Jr. or mail your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, CA 92612-2506

If you have questions regarding the contents of this letter, please contact Yumi Hiramine, compliance officer, at (818) 226-1839 or Yumi.Hiramine@FDA.HHS.GOV.

Sincerely,

Katherine E. Jacobitz -S

Digitally signed by Katherine E. Jacobitz -S
Date: 2023.09.27 19:27:07 -07'00'

CAPT Katherine Jacobitz
Acting Director, Division of Pharmaceutical Quality Operations IV

KJ: yh