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

VIA EMAIL CONFIRMED DELIVERY
RETURN RECEIPT REQUESTED

December 8, 2022

Joshua Kent Miles, Pharm.D.
Owner and Pharmacist-in-Charge
Lynn Oaks Compounding Pharmacy
2220 Lynn Rd Ste 101
Thousand Oaks, CA 91360-8018
lynnoaksrxfax@gmail.com

Dear Dr. Miles:

From March 30, 2022, to April 15, 2022, U.S. Food and Drug Administration investigators inspected your facility, Lynn Oaks Compounding Pharmacy, located at 2220 Lynn Road, Suite 101, Thousand Oaks, CA, 91360. 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 drug products which put patients at risk.

FDA issued a Form FDA 483 to your firm on April 15, 2022. FDA acknowledges receipt of your facility's response, submitted on April 19, 2022. 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 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

[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.

Division of Pharmaceutical Quality Operations
19701 Fairchild Road, Irvine, CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

products you produced, such as benzocaine/lidocaine/tetracaine 6/6/4% cream, benzocaine 20% suspension and tetracaine 6% topical solution.

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 containment, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.
2. You used a non-pharmaceutical grade component in the formulation of a drug product.
3. Vermin was observed in your production area.

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. Each batch of drug product required to be free of objectionable microorganisms is not tested though appropriate laboratory testing (21 CFR 211.165(b)).
2. Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release (21 CFR 211.165(a)).
3. There is no written testing program to assess the stability characteristics of drug products (21 CFR 211.166(a)).
4. The calibration of instruments is not done at suitable intervals with provisions for remedial action in the event accuracy and/or precision limits are not met (21 CFR 211.160(b)(4)).

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(s) 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. We acknowledge your statement "…During and between compounding material, we use pharmaceutical grade (b) (4) …" You did not provide evidence that cleaning after compounding hazardous and highly potent drugs includes a deactivation step.
2. We acknowledge your statement that (b) (4) Digoxin is not commercially available and the standard was a "clean and reasonable alternative for hospice use." You did not provide evidence that the Digoxin reference standard is equal to or better than the Digoxin USP monograph. Additionally, your response did not provide evidence for the purchase of (b) (4) .
3. We acknowledge your statement that a fly was immediately removed, and not inside the ISO-5 hood, however, you did not provide a remediation plan to reduce or eliminate the ingress of vermin into the compounding room.

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 valid prescriptions for individually-identified patients prior to compounding and distributing drug products.

In addition, regarding issues related to the conditions of section 503A of the FDCA, you did not address the failure to receive valid prescriptions for individually-identified patients 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

[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.

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 in which you will do so.

Please identify your notification with unique identifier: **CMS # 647593.**

Send your electronic response 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 Jamie Dion, compliance officer, at (303) 236-3133 or jamie.dion@fda.hhs.gov.

Sincerely,

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

SP:jd