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

STATE REFERRAL LETTER

VIA EMAIL CONFIRMED DELIVERY

June 9, 2023

Anne Sodergren, Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, STE 100
Sacramento, CA 95833

Ref: CMS 647593, FEI 3021028639

Dear Ms. Sodergren:

The purpose of this letter is to refer to you, the California State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy you licensed, Lynn Oaks Compounding Pharmacy, located at 2220 Lynn Road, Siute 101, Thousand Oaks, California.

FDA inspected the firm from March 30, 2022, to April 15, 2022. You were informed of the inspection but did not accompany FDA investigators during the inspection.

A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/163497/download, with any nonpublic information redacted. In addition, an Untitled Letter was subsequently issued by FDA to this firm on December 8, 2022, which can be found at https://www.fda.gov/media/165512/download, also with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that the FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, FDA investigators observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm used a non-pharmaceutical grade component in the formulation of a

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drug product. Specifically, Analytical Standard Digoxin, was used as the active ingredient in producing Home Hospice EOL SUS. During the period of January to March 2022, the firm produced this drug pursuant to four patient-specific prescriptions.

2. Vermin was observed in the firm's production area. Specifically, a living insect was observed crawling on the exterior surface of the biological safety cabinet on the left side on 3/30/2022 in the "compounding room". The sliding door entry to the "compounding room" is always opened to the outside retail pharmacy area when producing non-hazardous drugs, and is closed only when producing hazardous drugs. For example, the door in the "compounding room" was open while your non-sterile technician produced DICL/KETO/LIDO 2.5/10/7.5 Cream on 4/1/2022 and Clarithromycin 375 mg on 4/5/2022.

Lynn Oaks Compounding Pharmacy committed to FDA in its response to the Untitled Letter, received December 27, 2023, to correct some of the deviations in the Untitled Letter. In addition, the deviations identified appear to be readily correctable.

After review of the records, the FDA does not intend to take further action at this time with regard to the findings of this inspection. The FDA believes that the corrective actions can be appropriately overseen by the state. Therefore, the FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with human or animal drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Andrew Haack, compliance officer, at 206-340-8212, or by email at Andrew.Haack@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

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

Cc: Joshua Kent Miles, Pharmacist-In-Charge
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