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

VIA EMAIL CONFIRMED DELIVERY

July 8, 2020

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

Dear Ms. Sodergren:

The purpose of this letter is to refer to the California State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA's) concerns about practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Pacifica Pharmacy, located at 23560 Madison Street, Torrance, CA (Community Pharmacy license #PHY 39761).

FDA inspected the firm from August 26, 2019 to September 9, 2019. The California BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/132021/download 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 FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or 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 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Pacifica Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigator 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:

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1. Production of hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination. Specifically,

    a. The firm compounded hazardous drugs in the same areas and with the same equipment as non-hazardous drugs. Hoods, utensils and equipment are shared between hazardous and non-hazardous drug products.

    b. The firm had not determined the adequacy of the cleaning agent used to decontaminate and deactivate surfaces contaminated with hazardous drug compounds. Cleaning between all compounded products included only a wipe down of the compounding area/compounding hood using a cleaning agent where adequacy has not been established. In addition, the firm could not provide evidence that the detergents used to wash utensils and equipment remove hazardous drug residues.

    c. Compounding work surfaces and equipment were found to be contaminated with unknown powders and residue. These powders and residues were observed on wires and a power strip located in the back of a compounding hood, less than a foot from compounding activities. In addition, the balance used to weigh ingredients for compounding in the firm's hood had a build-up of material.

2. Use of a non-pharmaceutical grade component in the formulation of a drug product. Specifically,

    a. An expired and improperly stored component, Vitamin A Palmitate in Almond Oil, was used in the formulation of a drug product. This product expired on 1/1/2019 but was used in the compounding of 21 products between May and August 2019. The Vitamin A Palmitate in Almond Oil component was stored at room temperature despite the label requiring refrigerated storage.

Pacifica Pharmacy committed to FDA in its response to the Form FDA 483, received September 26, 2019, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the California BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs 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.

Sincerely,

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

SP: ah

Cc: Jeffrey A. Barris
President
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