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

December 6, 2019

Anne Sodergren
Interim 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) concerns about practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Jajco Inc. dba Anchor Drugs Pharmacy, located at 161 S. Spruce Avenue, South San Francisco, CA 94080-4517 (License Number PHY 48787).

FDA inspected the firm from October 24, 2018, through October 29, 2018. California BOP was 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/120630/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. 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 Anchor Drugs 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. In the response to the Form FDA 483, received on September 12, 2019, the firm advised FDA that it has "ceased all compounding (sterile and non-sterile). Sterile compounding was ceased September 2016 and non-sterile compounding as of January 2019."

Additionally, during the inspection, the 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:

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1. The firm produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination. Specifically, the firm's cleaning of utensils, equipment, and work surfaces is inadequate. The equipment used by the firm to mix drug substances, including testosterone and estradiol, is cleaned in a dishwasher using store bought detergent. The firm also uses dish soap and lint free wipes to clean the encapsulation equipment and unguator blade shafts. The firm does not use dedicated equipment for hazardous drugs and the cleaning process is inadequate to prevent cross-contamination.

2. Non-microbial contamination was observed in the firm's production area. Specifically, during production of Tylosin 50 mg capsules and Trilostane 35 mg/ml solution in the firm's hood, product residue was observed built up on the sides of the hood. The firm does not clean these areas as part of the routine cleaning operations. This hood is used to compound non-sterile human and animal drugs as well as hazardous drugs including, but not limited to testosterone and estradiol.

Anchor Drugs Pharmacy committed to FDA in its responses to the Form FDA 483 dated December 14, 2018, and September 12, 2019, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions.

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 State 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 Lance De Souza, Compliance Officer, at 510-337-6873, or by email at Lance.DeSouza@fda.hhs.gov.

Sincerely,

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

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