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

VIA UPS SIGNATURE CONFIRMED DELIVERY

July 8, 2019

Anne Sodergren
Interim Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834

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 poor practices observed during an FDA inspection at a pharmacy licensed by the California BOP, San Diego Compounding Pharmacy, located at 5395 Ruffin Road, Suite 104, San Diego, CA 92123-1338 (License Number PHY 47015).

FDA inspected the firm from October 17, 2018, to October 25, 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/120628/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 San Diego Compounding 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.

During the inspection, the FDA investigators observed deviations from appropriate non-sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, hazardous drugs were produced without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.

San Diego Compounding Pharmacy committed to FDA in its response to the Form FDA 483, 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.

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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. During your next routine inspection, we recommend that you ensure that the firm is utilizing water (e.g., Purified Water, USP or better) suitable for its intended use in the production of non-sterile drug products.

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 Jessica Mu, Compliance Officer, at 949-608-4477.

Sincerely,

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

SP: my

CC:

Jerome A. Greene
Owner/Pharmacist
San Diego Compounding Pharmacy
5395 Ruffin Road, Suite 104
San Diego, CA 92123-1338