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

VIA SIGNATURE CONFIRMED DELIVERY

November 22, 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 poor non-sterile practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Kohana Pharmacy and Center for Regenerative Medicine, Inc., located at 181 Tank Farm Road, Suite 120, San Luis Obispo, CA 93401-7082 (License Number PHY 50264).

FDA inspected the firm from April 10-17, 2019. 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/124963/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 investigator reviewed a small sample of records for products compounded by Kohana Pharmacy and Center for Regnerative Medicine 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 non-sterile 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. Non-phamaceutical grade components were used in the formulation of non-sterile drug products including but not limited to:

    - Loperamide HCl Oral 1 mg/5mL Suspension Lot # 03182019@23
    - 7+DBCGT: Diclofenac, Baclofen, Cyclobenzaprine, Gabapentin, Tetracaine 3%, 2%, 2%, 6%, 2% Cream Lot # 04032019@7
    - Lidocaine 2%/Mylanta/Diphenhydramine/Nystatin/Prednisolone Liquid Lot # 04082019@28
    - Ketamine Nasal Spray 100 mg/ml Lot # 03182019@35
    - Dyclonine HCl Solution 1% Lot # 03252019@32
    - Oxytocin Nasal Spray 40 units/mL Lot # 04012019@35
    - Itraconazole/EDTA/Gentamycin 2%/0.1%/0.25% Nasal Spray Lot # 04082019@36

2. Hazardous drugs were produced without providing adequate cleaning of work surfaces and/or cleaning of utensils to prevent-cross contamination.

Kohana Pharmacy and Center for Regenerative Medicine committed to FDA in its response to the Form FDA 483, received May 1, 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 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 Maria Kelly-Doggett, Compliance Officer, at 425-302-0427, or by email at maria.kelly-doggett@fda.hhs.gov.

Sincerely,

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