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

November 27, 2020

Anne Sodergren
Executive Director
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 sterile practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Sanders Pharmaceuticals, Inc. dba Rancho Park Compounding Pharmacy, located at 10587 W Pico Blvd, Los Angeles, CA 90064 (Retail Pharmacy Permit #50485).

FDA inspected the firm from April 23, 2019, to May 7, 2019. 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 investigator's observations from the inspection can be found at https://www.fda.gov/media/128374/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 investigator reviewed a small sample of records for products compounded by Sanders Pharmaceuticals, Inc. dba Rancho Park 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.

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

1. The ISO-classified areas were observed to be difficult to clean, particle-generating, or have visibly dirty equipment or surfaces.

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2. Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

3. Cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

4. Inadequately or un-protected components intended to be sterile were observed to be exposed to lower than ISO 5 quality air.

5. Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

6. The facility was designed and/or operated in a way that permitted poor flow of personnel and materials.

Sanders Pharmaceuticals, Inc. dba Rancho Park Compounding Pharmacy committed to FDA in their initial responses to the Form FDA 483, on May 28, 2019, and June 6, 2019, to correct the deviations in the Form FDA 483. Updates to these responses were received electronically by FDA on August 19, 2019, January 7, 2020, April 7, 2020, and June 22, 2020. In summation, these responses provided documentation in support of their corrective actions, including implementation of their new production suite which was scheduled to be operationally qualified by August 25, 2020. 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 CAPT Matthew Dionne, Compliance Officer, at 303-236-3064, or by email at Matthew.Dionne@fda.hhs.gov.

Sincerely,

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

SP:mrd