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

VIA EMAIL CONFIRMED DELIVERY

July 6, 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) concerns about practices observed during an FDA inspection at a pharmacy licensed by the California BOP, ABC Pharmacy, Inc., dba ABC Compounding Pharmacy, located at 16311 Ventura Blvd., Suite 110, Encino, CA (license number: PHY 49183).

FDA inspected the firm from December 12, 2019 to December 20, 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/134904/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 ABC Pharmacy, Inc., dba ABC 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 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 released a drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically,
    a. Progesterone SR 50 mg lot # 082416, was tested by a third-party-contract laboratory on 9/19/2016 and the potency was found to be 84.6%. The product was released for dispensing on 8/24/2016.
    b. The firm produced DILT/LIDO 2/5% ONT Lot# Di2Li5101819 and was assigned a beyond use date of 11/18/2019. The firm dispensed the product on 11/22/2019, again on 11/22/2019 and on 12/03/2019, which are in excess of the beyond use date assigned to the product.

2. Hazardous drugs were produced without providing adequate cleaning of utensils to prevent cross-contamination. Specifically, a spatula with a wooden handle was used to produce hazardous drug products.

ABC Pharmacy, Inc., dba ABC Compounding Pharmacy, committed to FDA in its response to the Form FDA 483, received January 21, 2020, to correct the deviations in the Form FDA 483. Some documentation was included in this response to support these corrections but not all corrections were supported. 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 any human or animal 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