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

September 29, 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 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, Safeway, Inc. dba Safeway Compounding Pharmacy, located at 6100 Hellyer Avenue, Suite 100, San Jose, CA 95138-1057 (Community Pharmacy license #53416; expires January 1, 2021 and Sterile Compounding license #LSC 100758; License Status: Cancelled; expired January 1, 2020).

FDA inspected the firm from June 5, 2017, to June 12, 2017. 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/133121/download, with any nonpublic information redacted. Additionally, FDA issued an Untitled Letter to the firm on March 27, 2019. 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 sample of records for products compounded by Safeway 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 sterile practice standards that, if not corrected, could lead to contamination of drugs,

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potentially putting patients at risk. Examples of deviations observed during our inspection include:

- Surfaces of the ISO 5 laminar airflow hood are not easily cleanable. Cracks were visually observed in the plexiglass sides panels. Exposed fluorescent light bulbs and electrical wiring were also observed in the ISO 5 laminar airflow hood.

Safeway Compounding Pharmacy committed to FDA in its response to the Form FDA 483, dated June 26, 2017 and January 10, 2018 as well as its response to the Untitled Letter, dated May 7, 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 BOP for follow up to ensure appropriate corrective action is taken. In your review of the disinfectants used at this firm, we recommend that you evaluate if the firm is utilizing sterile disinfectants within the ISO 5 areas and to clean anything including equipment that is introduced inside these areas as to prevent the introduction of contamination.

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 William V. Millar, Compliance Officer, at (503) 671-9711 Ext. 30, or by email at william.millar@fda.hhs.gov.

Sincerely,

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

SP:wm

Cc: Karen L. Muir
Pharmacist-in-Charge
Safeway Incorporated
6100 Hellyer Avenue, Suite 100
San Jose, CA 95138-1057