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

VIA EMAIL CONFIRMED DELIVERY

May 23, 2023

Anne Sodegren, Executive Officer
California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Ref: CMS 476521, FEI: 3011924560

State Referral Letter

Dear Ms. Sodegren,

The purpose of this letter is to refer to you, the California 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 you licensed, Burt's Pharmacy LLC, located at 2333 Borchard Road, Newbury Park, CA 91320.

The FDA inspected the firm from October 4, 2022, to October 7, 2022. You were informed of the inspection and the FDA investigators were accompanied by your state investigator for part of 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/163429/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 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 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for drug products compounded by Burt's Pharmacy, LLC and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

U.S. Food & Drug Administration
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Office of Pharmaceutical Quality Operations, Division IV
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During the inspection, the FDA investigators 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:

1. Use of non-pharmaceutical grade components were used in the formulation of drug products.

2. The firm produced hazardous drugs without providing adequate cleaning of equipment, work surfaces and utensils to prevent cross-contamination. For example, accumulation of loose powder and residue was observed in capsule equipment, rollers, mill, and hoods; the firm uses dish soap to clean utensils, equipment and work surfaces in rooms without evidence it can remove and deactivate hazardous compounds; and utensils are not easily cleanable.

3. Drug product was released in which the strength differs from, or it's purity or quality falls below that which it purports or is represented to possess. Specifically, the passing potency test result of Liothyronine T3 capsule, lot 02142022 was based on the average of two results and not based on each reported result without scientific rationale.

4. Vermin was observed in the production area. Specifically, a live spider was observed crawling on the counter and sink in the hazardous production room.

Burt's Pharmacy LLC committed to the FDA in its response to the Form FDA 483 received November 14, 2022, 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 records, the FDA does not intend to take further action at this time with regard to the findings of this inspection. The FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, the FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products 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 Yumi Hiramine, compliance officer, at (818) 226-1839, or by email at yumi.hiramine@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

CDR Steven Porter
Division of Pharmaceutical Quality Operations IV

SP: yh

Cc: Robert Leark, Owner

Burt's Pharmacy LLC
2333 Borchard Road
Newbury Park, CA 91320