



April 14, 2020

Dmitry Kunin
Program Director
Colorado State Board of Pharmacy
1560 Broadway, Suite 1350
Denver, CO 80202-5143

Dear Mr. Kunin:

The purpose of this letter is to refer to the Colorado 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 Colorado BOP, Professional Pharmacy Services Inc., dba Good Day Pharmacy, located at 1749 Main Street, Unit D, Longmont, CO 80501-7441 (Prescription Drug Outlet In-State License # PDO.0800000004).

FDA inspected the firm from June 10, 2019 to June 17, 2019. Colorado 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/130542/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 Good Day 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:

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

1. The firm produced highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.
2. The firm used a non-pharmaceutical grade component in the formulation of a drug product.

Good Day Pharmacy committed to FDA in its response to the Form FDA 483, dated July 5, 2019, and July 15, 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 Colorado 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 R. 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

Cc: Professional Pharmacy Services, Inc.
Ms. Vickilee K. Einhellig RPh, Co-Owner and CEO
1749 Main Street Unit D
Longmont, CO 80501-7441