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

November 23, 2020

Dmitry Kunin
Program Director
1560 Broadway, Suite 1350
Denver, CO 80202-5143

Dear Mr. Kunin:

The purpose of this letter is to refer to the Colorado 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, Infusion Treatment Center, Inc. dba I.T.C. Compounding and Natural Wellness Pharmacy, located at 651 Topeka Way, Suite 600, Castle Rock, CO 80109 (License #PDO.0370000018).

FDA inspected the firm from July 12, 2019, through July 23, 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/130570/download, with any nonpublic information redacted. Additionally, FDA issued an Untitled Letter to the firm on August 18, 2020 (https://www.fda.gov/media/143853/download). 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 observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, during our inspection we observed that the firm produced hazardous products as well as non-hazardous products with shared equipment, work surfaces, and utensils without adequate cleaning. Additionally, we observed deteriorated equipment and utensils, and non-pharmaceutical grade (b) (4) used in drug production.

I.T.C. Compounding and Natural Wellness Pharmacy committed to FDA in its response to the Form FDA 483 as well as its response to the Untitled Letter, dated August 8, 2019, and September 14, 2020, respectively, to correct the deviations in the Form FDA 483 and Untitled Letter, and provided documentation in support of those corrective actions.

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After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Colorado 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 via email at Matthew.Dionne@fda.hhs.gov or by phone at (303) 349-0301.

Sincerely,

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

SP: mrd

CC:

Allan Jolly, R.Ph., Owner
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