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

VIA EMAIL CONFIRMATION DELIVERY

September 13, 2021

Trina Crawford
Interim Executive Director, Pharmacy Quality Assurance Commission
Washington State Department of Health
PO Box 47852
Olympia, WA 98504-7852

Dear Ms. Crawford:

The purpose of this letter is to refer to the Washington State Department of Health (DOH) 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 Washington DOH, First Pharma Associates, LLC dba Riverpoint Pharmacy, located at 1802 North Monroe Street, Spokane, WA 99205-4528 (Pharmacy License #PHAR.CF.60801539; expires 5/31/22).

FDA inspected the firm from February 23, 2021, to March 3, 2021. Washington DOH 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/151143/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 investigators reviewed a small sample of records for products compounded by First Pharma Associates, LLC dba Riverpoint 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 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:

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

1. The firm produced high potent drugs without using an adequate cleaning agent to clean equipment and parts to prevent cross-contamination. For example, an expired cleaning agent was used to clean equipment and parts.
2. A balance located inside a hood in the hazardous compounding room had neither a calibration sticker due date nor a daily weight check logbook.
3. There is no storage temperature and storage condition requirements once a completed ointment compounded product is produced and kept in its container until it is needed to fill a prescription.
4. The cleaning of non-dedicated mixing equipment parts used in the ointment production is unknown.
5. An out-of-specification (OOS) investigation was not performed when potency test results failed for Liothyronine lot 12082020@ compounded on December 8, 2020.

First Pharma Associates, LLC dba Riverpoint Pharmacy committed to FDA in its response to the Form FDA 483, on March 16, 2021, to correct the deviations in the Form FDA 483. 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. Therefore, FDA is referring this matter to the Washington State DOH 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 Mariza Jafary, Compliance Officer, at 949-608-2977, or by email at Mariza.Jafary@fda.hhs.gov.

Sincerely,

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

SP: mj

Cc: Erik Nelson, PharmD (via email)
Pharmacist-In-Charge and Owner
First Pharma Associates, LLC dba Riverpoint Pharmacy
1802 North Monroe Street
Spokane, Washington 99205