U.S. FOOD & DRUG ADMINISTRATION

May 3, 2023

Donna Yeatman, Executive Secretary
Alabama State Board of Pharmacy
111 Village Street
Birmingham, AL 35242

Ref: CMS WA 485545, FEI 3013497126

State Referral Letter

Dear Ms. Yeatman:

The purpose of this letter is to refer to you, the Alabama State 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, Triad Rx, Inc. (Triad), located at 26258 Pollard Road, Daphne, AL 36526-4250.

FDA inspected the firm from December 5, 2022, to December 8, 2022. You were 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/164462/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 investigator reviewed a small sample of records for drug products compounded by Triad 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).

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.Triad committed to FDA in its response to the Form FDA 483

U.S. Food & Drug Administration
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Office of Pharmaceutical Quality Operations, Division II
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December 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, 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 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 Rebecca Asente, Compliance Officer, at (504) 846-6104, or by email at Rebecca.asente@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Ronda R. Loyd-jones -S

Digitally signed by Ronda R. Loyd-jones -S
Date: 2023.05.03 12:16:32 -07'00'

Ronda R. Loyd-Jones
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Matt McDonald, Owner
Triad Rx, Inc.
26258 Pollard Road
Daphne, AL 36526-4250