U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100
Fax: (313) 393-8139
www.fda.gov

June 16, 2022

Kimberly A. Grinston
Executive Director
Missouri Board of Pharmacy
3605 MO Blvd.
Jefferson City, Mo., 65109

Ref: FEI 3013446837

State Referral Letter

Dear Ms. Grinston:

The purpose of this letter is to refer to you, the Missouri Board of Pharmacy (MO-BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy you licensed, Accurate Rx Pharmacy Consulting, LLC dba Optum Infusion Pharmacy, located at 103 Corporate Lake Drive, Suite B, Columbia, Missouri.

FDA inspected the firm from July 6, 2021, to July 15, 2021. FDA investigators were accompanied by your state investigators 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/152619/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 Accurate Rx Pharmacy Consulting, LLC dba Optum Infusion

Pharmacy 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 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. Pharmacy employees were observed cleaning the ISO 5 laminar air flow hood with non-sterile wipes and non-sterile cleaning agents.
2. During cleaning of the ISO 5 classified aseptic processing area, pharmacy employees did not clean difficult to clean surfaces or equipment within the hood.
3. Pharmacy employees were observed bringing supplies into aseptic processing areas without first disinfecting them.

Accurate Rx Pharmacy Consulting, LLC dba Optum Infusion Pharmacy committed to FDA, in a response letter dated February 28, 2022, to correct the deviations 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 Tina M. Pawlowski, Compliance Officer, at (313) 393-8217, or by email at tina.pawlowski@fda.hhs.gov. Please use the reference number cited in the heading of the document.

Sincerely,

Jeffrey D. Meng -S

Digitally signed by Jeffrey D. Meng -S
Date: 2022.06.16 10:16:22 -04'00'

Jeffrey Meng
Program Division Director
Office of Pharmaceutical Quality and Operations, Division III

Cc:

Jeffrey Lyons
General Manager
Optum Infusion Services
15529 College Blvd.
Lenexa, Ks. 66219