DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Kansas District Office
8050 Marshall Drive, Suite 205
Lenexa, KS 66214
Telephone: (913) 495-5100
Fax: (913) 495-5115

March 10, 2016

Kimberly A. Grinston, JD, Executive Director
Missouri Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625

Dear Ms. Grinston:

The purpose of this letter is to bring to the attention of the Missouri Board of Pharmacy the U.S. Food and Drug Administration's (FDA) concern about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Missouri Board of Pharmacy, Triad Isotopes, Inc., located at 712 Westport Road, Kansas City, Missouri 64111-3130. The inspection occurred from January 5, 2015, to January 9, 2015. The FDA's investigators were accompanied by an inspector from the Missouri Board of Pharmacy for the inspection. Attached is a redacted copy of the Form FDA 483 that documents our investigator's observations from the inspection, and a copy of the warning letter issued based on observations made during the inspection.

The FDA investigators observed deviations from appropriate sterile practice standards that could lead to contamination of drugs, putting patients at risk. The warning letter FDA sent Triad Isotopes, Inc. identifies violations of the Federal Food Drug and Cosmetic Act (FDCA). Drug products that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing them to be adulterated (section 501(a)(2)(A)). Due to the nature of the violations, FDA intends to follow up with the firm regarding correction of the insanitary conditions.

We ask that you 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 further 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 Danial Hutchison, Compliance Officer, via email at danial.hutchison@fda.hhs.gov or by phone at (913) 495-5154.

Sincerely,

for Cheryl A. Bigham
District Director
Kansas City District

Attachments: Redacted 483