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

May 3, 2018

UPS NEXT DAY
SIGNATURE REQUIRED

Marc Pfefferle
Chief Executive Officer
Triad Isotopes, Inc.
4205 Vineland Road, Suite L1
Orlando, FL 32811-6628

Dear Mr. Pfefferle:

From June 26, 2017, to July 3, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Triad Isotopes, Inc., located at 712 Westport Road, Kansas City, MO 64111-3130.

FDA issued a Form FDA 483, Inspectional Observations, to your firm on July 3, 2017. FDA acknowledges receipt of your facility's responses, dated July 24, 2017, and August 28, 2017. Based on this inspection, it appears your firm is producing drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)]. Section 503A does not apply to the compounding of radiopharmaceuticals (section 503A(d)(2)).

On December 28, 2016, FDA issued a draft guidance titled, *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities* (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM534811.pdf).[1] This draft guidance describes the conditions under which FDA does not intend to take action for violations of new drug requirements, labeling with adequate directions for use requirements, and current good manufacturing practice (CGMP) requirements when a State licensed nuclear pharmacy

[1] When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of this guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

or Federal facility that is not an outsourcing facility compounds or repackages radiopharmaceuticals for human use.

Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provision of the FDCA related to the production of drugs, including the requirement that the drug products not be prepared, packed, or held under insanitary conditions (section 501(a)(2)(A)).

B. Violations of the FDCA

Adulterated Drug Products

During the inspection, the FDA investigator observed that drug products 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 your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that your firm used non-sterile disinfectants in the ISO 5 aseptic processing areas, did not use a sporicidal agent in the ISO 5 areas, and did not monitor permanent equipment in the ISO 5 hood for microbial contamination.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)] the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your firm's responses to the Form FDA 483. Some of your corrective actions appear to be adequate to address insanitary condition observations on the Form FDA 483.

However, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. Your response commits to implementing the use of a sporicidal agent in the ISO 5 aseptic processing areas on a (b) (4) basis. However, the updated cleaning and disinfecting procedure submitted does not identify a specific sporicidal agent (or sporicidal options) or the specific contact times that are required when used.

We will evaluate the adequacy of all your corrective actions at a future inspection.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing if you have taken any steps to correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please address your reply via email to: ORAPharm3_Responses@fda.hhs.gov.

Attn: Eric Mueller
Compliance Officer
U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III

Refer to the Unique Identification Number (Case# 543176) when replying. If you have questions regarding the contents of this letter, please contact Mr. Mueller at (402) 331-1101.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001200033, cn=Nicholas F. Lyons -S
Date: 2018.05.03 13:00:31 -05'00'

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III

cc: Joseph M. Huber
Pharmacy Manager
Triad Isotopes, Inc.
712 Westport Road
Kansas City, MO 64111