DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/30/2026-4/2/2026
	FEI NUMBER 3013422537

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brian T. Schmedding, Senior QC Production Specialist

FIRM NAME	STREET ADDRESS
Ionetix Corporation	1950 S Tamiami Trl
CITY, STATE, ZIP CODE, COUNTRY Sarasota, FL 34239-3603	TYPE ESTABLISHMENT INSPECTED Positron Emission Tomography Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
Facilities and Equipment System

OBSERVATION 1

You did not implement procedures and document your activities in accordance with your procedures to ensure that all equipment is suitable for its intended purposes and properly installed, maintained, and capable of repeatedly producing valid results that could reasonably be expected to adversely affect the identity, strength, quality, or purity of a PET drug, or give erroneous or invalid test results when improperly used or maintained.

Specifically, your facility has manufactured (b)(4) in[(b)(4)] ml (b)(4) syringes for use in patients since 11/29/2022 for an estimated total of (b)(4) syringes. On 3/31/2026, I observed that the ISO-5 Hood[(b)(4)] (LAFH) had a magnehelic gauge for air pressure that was not operational and lights in the hood on the upper right and left appeared to be placed in a way that would disrupt first air for aseptic operations. Aseptic operations include the collection of samples of (b)(4) for endotoxin and sterility testing and sterile (b)(4) into[(b)(4)] ml patient (b)(4) syringes.

Materials System

OBSERVATION 2

You did not use a reliable supplier as a source of each lot of component.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne E King, Investigator X Joanne E King Investigator Signed By: 1300174867 Date Signed: 04-02-2026 16:54:45	4/2/2026

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Specifically, (b)(4) purity with the Ionetix specification (b)(4) is manufactured in a facility that is not registered with the Agency. This (b)(4) is used as (b)(4) for the HPLC (b)(4)). These PET drugs (b)(4) and (b)(4) to make up the (b)(4) material. This (b)(4) material is used to make (b)(4) Your (b)(4) in (b)(4) ml syringe (containing (b)(4) ml) is part of an abbreviated new drug application PET drug product that is manufactured using this component.

OBSERVATION 3
You did not approve or reject, before implementation, specifications to ensure that they maintain the identity, strength, quality, and purity of a PET drug.

Specifically, you did not have an assigned item number or specification for the (b)(4) ml (b)(4) vial and caps used to hold and transfer the (b)(4) lot (b)(4) QC sub batch sample on (b) (4) to the QC lab for release testing for pH, radiochemical identity and purity, and bacterial endotoxin.

Production System

OBSERVATION 4
You did not have written production and process control procedures to ensure that any deviations from the procedures are justified.

Specifically, the following process control procedures did not reflect in writing the procedures that were implemented on (b)(4) during the manufacture of (b)(4) lot (b)(4) :

A. *SOP QC-010 Radiochemical Identity and Purity of* (b)(4) *Via* (b)(4) *Chromatography* (b)(4) *C) rev. 7 eff. 11/20/2025 Section 7.21* included the instructions to (b)(4)

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(b)(4) (b)(4) final product ((b)(4) at the origin of the (b)(4) plate.

On 3/31/2026, I observed that (b)(4) of (b)(4) lot (b)(4) was (b)(4) onto a (b)(4) plate and that this was not a (b)(4) sample.

B. *SOP QC-002 Radionuclidic Identity by Half-Life and Radioconcentration rev. 4 eff. 12/22/2020 Sections 7.6 and 7.7* included the instructions to record the (b)(4) to the final product container closure and to use this (b)(4) to calculate the radioactivity concentration in (b)(4)

On 3/31/2026, I observed that the (b)(4) to the fina(b)(4) ml syringe was not recorded or used in the final product radioactive concentration calculation for (b)(4) lot (b)(4) The total final finished product volume of(b)(4) ml was entered into the e-batch record and used to calculate the radioactivity concentration in (b)(4)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."