DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	4/13/2026-4/17/2026
	FEI NUMBER 3038545356

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph M. DeSimone, Vice Chair of Strategy, Department of Radiology

FIRM NAME	STREET ADDRESS
Molecular Imaging Program at Stanford	1701 Page Mill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Palo Alto, CA 94304-1210	PET 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 WE OBSERVED:

OBSERVATION 1

Your batch production record does not include each major production step (obtained from the approved appropriate master production and control record).

Specifically,

Your firm's master batch production records for (b)(4) Injection, do not document all production operations conducted in the (b)(4) hot cell, including the aliquoting of product from the bulk finished product vial into multiple multidose vials for distribution to radiopharmacies.

Additionally, the master batch record for (b)(4) Injection used for production of the FDA submission batches completed on (b)(4), lot (b)(4), (b)(4) lot (b)(4), and (b)(4), lot (b)(4), was not approved for use until 6/9/2025.

OBSERVATION 2

You did not establish and follow procedures to ensure that each batch or sub-batch of a PET drug product was given final release until an appropriate laboratory determination was completed.

Specifically,

Sterility testing for (b)(4) injection is not conducted on the (b)(4) vial(s) that would be distributed to radiopharmacies for patient dosing administration. Your current practice is to

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EMPLOYEE(S) SIGNATURE
Zachary L Stamm, Investigator
Matthew R Clabeaux, Investigator
Sateesh Kum Sathigari, FDA Center Employee

X Zachary L Stamm Investigator Signed By: ZACHARY L STAMM -S Date Signed: 04-17-2026 12:31:04

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conduct sterility testing on your (b)(4) product vial prior to aliquoting into the (b)(4) vial(s).

OBSERVATION 3

You did not establish and follow written quality assurance procedures.

Specifically,

A) Your firm does not have a written procedure for labeling of (b)(4) vials that would be distributed to radiopharmacies. Your firm's management stated the practice for (b)(4) vials would be to not individually label the (b)(4) vials but label the vial shielding "Pig" when distributed. There are no controls to ensure labeling accuracy, prevent labeling errors, or verify that labels are complete and correct.

B) Your firm has no written procedures for preventive maintenance of production and laboratory equipment. As such, there are no procedures specifying:

- What maintenance activities must be performed
- The frequency of preventive maintenance
- Acceptance criteria for maintenance activities
- Documentation requirements
- Personnel responsible for performing and verifying maintenance

Examples of equipment lacking preventive maintenance procedures include:
Production Equipment:

- (b) (4)
- (b)(4) Unit
- ISO Class 5 (b) (4) Hot Cell
- ISO Class 5 Laminar Flow Hood

Laboratory Equipment:

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- Gas Chromatography System

A) Attachments to your firm's standard operating procedures that are integral to production and quality control operations, such as logs (e.g., receipt of incoming materials and components, equipment use) and forms (e.g., cleaning of the (b) (4) hot cell and gowning validation report), do not have approval signatures from the quality control unit, are not subject to the firm's document approval process, and do not have documented effective dates.

OBSERVATION 4

Each laboratory did not have sampling and testing procedures which are designed to ensure that PET drug products conform to appropriate standards including established standards of identity, strength, quality and purity.

Specifically,

A) Your firm does not conduct growth promotion testing on purchased microbial media used to conduct media fill simulations, aseptic operator qualification, sterility testing and environmental monitoring for the production of (b)(4) Injection.

B) Your firm does not have written procedures governing user account access and credential management for analytical computer data systems in your Quality Control laboratory.

On April 15, 2026, we observed that management had received login credentials via text message for a radiochemist to access another employee's user account who was not present on-site.

C) Your firm has not established procedures for qualifying primary analytical equipment used in your quality control lab to test PET drug products manufactured at your facility. Your firm uses the following gas chromatography (GC) systems as primary analytical instrumentation for residual solvent testing to support (b)(4) Injection product release:

- Gas Chromatography (b)(4), Equipment ID: CRF_E00086, Serial Number: (b)(4)

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- Gas Chromatography (b)(4)) System, Equipment ID: CRF_E00082, Serial Number: (b)(4)
- (b)(4)), Equipment ID: CRF_E00083, Serial Number: (b)(4)

These instruments are identified in your firm's (b)(4) , as the primary analytical instruments for residual solvent testing and are currently being used for batch release testing. Your firm could not provide documentation to demonstrate qualification of this laboratory equipment.

D) Your firm does not have procedures that require excel sheets used in your Quality Control laboratory to be controlled, qualified, and approved prior to use. For example, your firm used your (b) (4) Production QC Calculations" Excel sheet to conduct gas chromatography calculations as part of finished product conformance and release testing of (b)(4) registration batches of (b)(4) Injection batches for (b)(4) .

OBSERVATION 5

Each laboratory used to conduct testing of finished PET drug products does not have written procedures for the conduct of each test.

Specifically,

Your firm has not validated your in-house test method, (b)(4) which is used for residual solvent testing to support (b)(4) Injection drug product release.

This test method has been used to test the following (b)(4) Injection batches for application submission, release, and performance qualification:

- Lot (b)(4) on (b)(4)

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	Zachary L Stamm, Investigator Matthew R Clabeaux, Investigator Sateesh Kum Sathigari, FDA Center Employee	X Zachary L Stamm Investigator Signed By: ZACHARY L. STAMM -S Date Signed: 04-17-2026 12:31:04	4/17/2026

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- Lot (b)(4) on (b)(4)
- Lot (b)(4) on
- (b)(4) on (b)(4)

OBSERVATION 6

You did not use a reliable supplier as a source of each lot of component, container and closure.

Specifically,

You are not following your firm's procedure titled, "Vendor Qualification", SOP QA.016, Revision A (effective 14 September 2025), which establishes requirements for vendor selection, approval, and oversight.

Your firm accepted raw materials on the CoA alone and failed to provide vendor qualification forms or questionnaires, vendor risk assessments, or any vendor qualification documentation for materials used in (b) (4) drug production including but not limited to:

- (b)(4) Tube, Lot (b)(4)
- (b)(4) Tubes, Lot (b)(4)
- (b)(4), Batch Number (b)(4)
- (b)(4), Sterile Lot (b)(4)
- Transfer tubing, with no documentation available for review

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You explained to the FDA Investigators that supplier qualifications were performed at the previous location and that practice has not been extended to the vendors/suppliers at the new location.

X Matthew R Clabeaux
Investigator
Signed By: Matthew R. Clabeaux -S
Date Signed: 04-17-2026 12:31:34

X Sateesh Kum Sathigari
FDA Center Employee
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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."