DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	5/18/2026-5/22/2026
	FEI NUMBER 3036193770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert M. Bougard, Regional Director of Operations, Southwest

FIRM NAME	STREET ADDRESS
PETNET SOLUTIONS, INC	8360 Camino Santa Fe
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92121-2658	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

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

Specifically,

Your firm failed to follow procedure SOP # D0011306 titled "Supplier Qualification, Approval, and Maintenance," Revision H (Effective Date: 11/1/2025), which establishes requirements for vendor selection, approval, and oversight. For example:

A. Your firm failed to show (b) (4) as an approved supplier of the precursor (b) (4) mg/vial), a critical component used in the manufacture of (b) (4) Injection. There are no supplier qualification activities performed prior to introducing the precursor (b) (4) into the manufacture of (b) (4) process validation (PV) batches of (b) (4) Injection (Batch #s(b) (4)

In addition, the HPLC identity test performed to receive the precursor raw material at central facility is not specific to confirm the identity of precursor that yields as an active ingredient.

B. Your firm accepted transfer tubing — a material used during product transfer in the manufacture of (b) (4) Injection — without obtaining a specification sheet to verify material specifications. In addition, there is no documentation to show that this supplier is qualified.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Linda Thai, Investigator Anney Lin, Investigator Cecilia H Kieu, Investigator Sateesh Kum Sathigari, FDA Center Employee X Linda Thai Investigator Signed By: 1300146654 Date Signed: 05-22-2026 14:28:09	5/22/2026

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OBSERVATION 2
An appropriate laboratory determination to ensure that each batch of a PET drug product conforms to specifications was not conducted before final release.

Specifically,

A. Your procedure D0001978, Product Test: Appearance, effective 10/23/24 is not adequate. The procedure does not include the use of contrast background for visual inspection of final product to determine visible particle matter, color and clarity.

B. The qualification (b) (4) used for qualification of visual inspection of the operators is not adequate. The (b) (4) of (b) (4) vials in which (b) (4) vials only contain (b) (4) of (b) (4) ((b) (4) particle). The (b) (4) is not representative for identifying all particulate matters and defects.

OBSERVATION 3
Your master production and control records did not include a statement of action limits on radiochemical yield.

Specifically,

A. The manufacturing batch records for (b) (4) Injection do not include action limits on radiochemical yield. For example, Manufacturing batch record for PPQ batch # (b) (4) on page 3 of 26 Section, Final Product Vial Assay and Sterility Inoculations, the radiochemical yield is only recorded, however, there is no statement on action limits on radiochemical yield beyond which investigation and corrective action are required.

B. The document (D0009777) "Investigations for Low Radiochemical Yields and Failed Batches in the

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Production (b) (4) Labeled Products," states that the action limit for radiochemical yield for (b) (4) (b) (4) labelled product as (b) (4). The firm cannot provide any scientific rationale for the (b) (4) action limit, considering the firm manufactured around (b) (4) batches of (b) (4) injection and the obtained yield for these batches was around 65%.

OBSERVATION 4

You lack personnel with the necessary background and training to perform their assigned functions.

Specifically,

On 05/19/2026, during a production mock preparation of final product vial subassembly conducted under the ISO 5 (b) (4) laminar airflow hood (LFH SN: (b) (4), the operator (b) (6), (b) (7) did not follow techniques described in SOP D0011940, *Preparation of Final Product Vial Subassembly* – (b) (4) (b) (4) Revision: Q, Effective Date: 03/13/2025.

The operator failed to follow aseptic techniques as specified in the instructions of SOP D0011940. For example:

A) The operator did not apply (b) (4) to their gloved hands prior to re-entering the ISO 5 critical zone.
B) The operator placed the environmental monitoring (EM) settle plate cover face up of the in the critical zone during active aseptic operations.
C) Materials and components were positioned in front of one another, obstructing first-air flow.
D) During the cleaning, the operator did not employ (b) (4) wipe strokes. In addition, the operator used wipes from an already opened package.
E) The operator did not (b) (4) and (b) (4) and (b) (4) on to the (b) (4) when performing personnel EM. We observed the operator conducted the personal EM with

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approximately (b) (4) motion touch for (b) (4) finger.

OBSERVATION 5

You did not implement procedures to ensure that all equipment is cleaned and suitable for its intended purposes 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,

You failed to monitor the pressure differential of ISO 5 Laminar Flow Hood (# (b) (4)), to ensure the pressure differential across the filter face to indicate the HEPA filters function appropriately during the final product vials assembly.

X Cecilia H. Kieu -S Digitally signed by Cecilia H. Kieu -S Date: 2026.05.22 14:29:51 -07'00'

X ANNEY LIN -S Digitally signed by ANNEY LIN -S Date: 2026.05.22 14:30:42 -07'00'

X SATEESH SATHIGARI -S Digitally signed by SATEESH SATHIGARI -S Date: 2026.05.22 14:31:45 -07'00'

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Linda Thai, Investigator Anney Lin, Investigator Cecilia H Kieu, Investigator Sateesh Kum Sathigari, FDA Center Employee	X Linda Thai Investigator Signed By: 1300146654 Date Signed: 05-22-2026 14:28:09	5/22/2026

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."