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	3/4/2026-3/6/2026
	FEI NUMBER 3009856092

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

FIRM NAME	STREET ADDRESS
PETNET Solutions, Inc.	6320 Annie Oakley Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89120-3972	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 I OBSERVED:

OBSERVATION 1

Your firm lacks adequate production and process controls to ensure the consistent production of a PET drug that meets the applicable standards of identity, strength, quality and purity.

Specifically,

A. Test procedures for performing bacterial endotoxin testing lack adequate instruction to prevent variability in sample handling that could produce inconsistent test results. For example, on 03/05/2026:

- the operator performing quality control endotoxin testing for PET drug, (b) (4) (b) (4)), Batch Number (b) (4) prepared the sample (b) (4), which then sat for approximately (b) (4) minutes prior to loading into the (b) (4) test cartridge. The operator did not (b) (4) the (b) (4) after sitting nor before testing.

- the operator performing quality control endotoxin testing for PET drug, (b) (4) Batch Number (b) (4) prepared the sample (b) (4), which then sat for approximately (b) (4) minutes prior to loading into the (b) (4) test catridge. The operator (b) (4) the sample (b) (4) by (b) (4) after sitting and immediately before testing.

Per SOP D008421 Product Testing: Bacterial Endotoxin Test – (b) (4) Method the sample (b) (4) is a (b) (4) of final product solution and sterile (b) (4) . The procedure fails to instruct a (b) (4) method, (b) (4) x time duration, or testing time frame after (b) (4).

B. There is no quarantine period for Final Product Vial (FPV) subassemblies to ensure they were

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jolanna A Norton, Investigator X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 03-06-2026 14:24:43	3/6/2026

produced under aseptic conditions prior to use during formulation and sterile (b) (4) of PET drugs. FPVs produced in conditions with action level microbiological recoveries (b) (4) CFU) were used for PET drug production prior to completion of EM sample incubation. For example:

- EM investigation, EML_INV0000929, reported action level growth (8 CFU, *Paenibacillus glucanolyticus*) recovered from the (b) (4) glove of ISO 5 operator following 12/19/2025 production of (b) (4) (b) (4) Final Product Vial Assemblies, Exp. (b) (4) Six of the (b) (4) FPVs produced on (b) (4) were used to produce batches of sterile PET drug, (b) (4) :

Batch Number	Production Date
(b) (4)	

A report of EM incubation readings shows 8 CFU growth was recorded on 12/24/2025.

OBSERVATION 2

You did not follow written quality assurance procedures.

Specifically,

On 03/05/2026 following production of (b) (4) FPVs, (b) (4) , in the ISO 5 Laminar Flow Hood, performing operator failed to collect EM personnel glove samples as instructed in written procedure, D00011940 Preparation of Final Product Vial Subassembly – (b) (4) . The procedure instructs operators to (b) (4) " (b) (4) glove finger on to surface of sample media. On 3/5/2026, the operator was observed (b) (4) fingertip onto media surface.

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EMPLOYEE(S) SIGNATURE

Jolanna A Norton, Investigator

X Jolanna A Norton
Investigator
Signed By: Jolanna A. Norton -S
Date Signed: 03-06-2026
14:24:43

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3/6/2026

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."