

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 2/9/2026-2/17/2026* FEI NUMBER 3011121261			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anna K. Wierzbicki, Pharmacy Manager					
FIRM NAME PETNET Solutions Inc		STREET ADDRESS 11100 Euclid Ave Rm S-106a			
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716		TYPE ESTABLISHMENT INSPECTED PET Drug Product 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 facilities are not adequate to ensure the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality. Specifically, A. You failed to assess, investigate or perform corrective and preventable actions (CAPA) following the recovery of a highly pathogenic and objectionable microorganism from inside your ISO 5 PEC Hot Cell-^{(b) (4)}. Your hot cell is comprised of an enclosed ISO 8 space surrounding and supporting a centrally located ^{(b) (4)} airflow ISO-5 Primary Engineering Control (PEC). For example, a 1 Colony Forming Unit (1 CFU) of fungal was recovered in your ^{(b) (4)} active air sampling of your ISO 5 PEC Hot Cell-^{(b) (4)} On 2/7/2025. In addition, 1 Colony Forming unit of <i>Aspergillus Hiratsukae shendawei</i> was recovered on 10/2/2024 and one colony forming unit (1 CFU) of <i>Talaromyces delawarensis</i> was recovered on 10/8/2024. You did not conduct an investigation further into the excursion of the ISO 5 PEC Hot Cell-^{(b) (4)}, implement corrective and preventable actions, nor did you identify the specie of the fungal organism recovered on 2/7/2025. Your SOP D0012135, "^{(b) (4)} Environmental Monitoring for Fungal "Revision K, dated 10/31/2020, had details those recoveries of 1 CFU of fungal in the ISO 5 PEC Hot Cell-^{(b) (4)} is handled as an alert action which is inadequate as it fails to investigate recoveries of 1 CFU of fungal in the ISO 5 PEC. B. Your Environmental monitoring program fails to include routine sampling of the supporting ISO 8 classified areas ^{(b) (4)} to the ISO 5 PEC area of the Hot Cell where sterile PET drug products are manipulated in an open state. For example, your environmental monitoring fails to include areas inside the hot cell even though numerous highly pathogenic and objectionable microorganisms have been identified during routine Environmental monitoring.					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator </td> <td style="width: 40%; vertical-align: top;"> Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-8 Date Signed: 02-17-2026 12:07:30 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-8 Date Signed: 02-17-2026 12:07:30 X
EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-8 Date Signed: 02-17-2026 12:07:30 X				
DATE ISSUED 2/17/2026					

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 2/9/2026-2/17/2026*
	FEI NUMBER 3011121261

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anna K. Wierzbicki, Pharmacy Manager

FIRM NAME PETNET Solutions Inc	STREET ADDRESS 11100 Euclid Ave Rm S-106a
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716	TYPE ESTABLISHMENT INSPECTED PET Drug Product Manufacturer

#	Date	Location	Investigation #	Description	CFU Count	Identification	Conclusion
1..	June 18, 2025	ISO 5 PEC HC- (b) (4)	EMH_INV0000997	Action limit Surface contact environmental monitoring (EM).	30	No identification obtained.	Lapse in aseptic technique
2.	April 3, 2025	ISO 5 laminar flow hood (LFH)	EML_INV0000863	Action Limit Passive air environmental monitoring (EM)	3	Penicillium Sp.	Plate mishandling
3.	February 20, 2025	ISO 5 laminar flow hood (LFH)	EML_INV0000854	Action Limit Personal Glove Environmental Monitoring	100	Staphylococcus hominis	Definitive Root cause Could not be determined
4.	May 15, 2025	ISO 5 PEC HC- (b) (4)	EMH_INV0000991	Action limit Surface contact environmental monitoring (EM).	13	Staphylococcus aureus, Micrococcus luteus, Staphylococcus Warneri, Staphylococcus epidermis, Moraxella osloensis, Peribacillus frigoritolerans, Peribacillus butanolivorans Staphylococcus hominis	Plate Mishandling

In addition, your environmental monitoring program fails to include routine sampling of the unclassified room accommodating the ISO-5 LFH used for the aseptic Finished Product Vial (FPV) Assembly even though several spore forming genera (bacillus Sp.) has been recovered in the ISO -5 LFH and from the gloves of operators who worked in the classified ISO 5 LFH between January 2024 to February 2026. This unclassified room are sampled during the biennial room certification process.

#	Date	Location	Investigation #	Description	CFU Count	Identification	Conclusion
1.	February 20, 2025	ISO 5 laminar flow hood	EML_INV0000854	Action Limit Personal Glove Environmental Monitoring.	100	Staphylococcus hominis	Definitive Root cause Could not be determined

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-S Date Signed: 02-17-2026 12:07:30 X	DATE ISSUED 2/17/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 2/9/2026-2/17/2026* FEI NUMBER 3011121261
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anna K. Wierzbicki, Pharmacy Manager
--

FIRM NAME PETNET Solutions Inc	STREET ADDRESS 11100 Euclid Ave Rm S-106a
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716	TYPE ESTABLISHMENT INSPECTED PET Drug Product Manufacturer

		(LFH)					
2.	March 7, 2025	ISO 5 laminar flow hood (LFH)	EML_INV0000860	Action Limit Personal Glove Environmental Monitoring.	15	Staphylococcus hominis	Plate Mishandling Event
3.	July 2, 2025	ISO 5 laminar flow hood (LFH)	EML_INV0000889	Action Limit Personal Glove Environmental Monitoring.	38	Staphylococcus epidermis	Aseptic technique lapses
4.	June 5, 2025	ISO 5 laminar flow hood (LFH)	NA	Alert liny Personal Monitoring	2	Niallia circulans, Paeniba callus provencensis/urinalis	NA Sporocidal cleaning remediation on 7/28-29/2025

C. Your current Environmental Monitoring program for alert and action level events that requires remediation (cleaning and disinfection). and you wait on microbiological identification of isolates and consultations from the corporate microbiologist staff for remediation and recommendations. This process takes multiple weeks between remediation activities and when they are completed and there are no time frames in the action item procedures to include mechanism used to assign remediation cleaning activities. You do not implement resampling response to previous microbial findings following sporocidal cleaning after micro recoveries in your ISO-5 PEC of the Hot Cell and ISO 5 LFH.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-S Date Signed: 02-17-2026 12:07:30 X	DATE ISSUED 2/17/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

550 Main Street, Ste 4-930
Cincinnati, OH 45202
(513) 322-0700 Fax: (513) 679-2772

DATE(S) OF INSPECTION

2/9/2026-2/17/2026*

FEI NUMBER

3011121261

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Anna K. Wierzbicki, Pharmacy Manager

FIRM NAME

PETNET Solutions Inc

STREET ADDRESS

11100 Euclid Ave Rm S-106a

CITY, STATE, ZIP CODE, COUNTRY

Cleveland, OH 44106-1716

TYPE ESTABLISHMENT INSPECTED

PET Drug Product Manufacturer

For Examples, I reviewed the following Environmental monitoring recoveries investigation reports with their associated action item and remediation actions:

#	Date of occurrence	Location	Investigation #	Description of Event	Identification	Conclusion	Date closed	Date of remediation
1..	June 18, 2025	ISO 5 PEC HC-(b) (4)	EMH_INV0000997	30 CFU Count Action limit Surface contact environmental monitoring (EM).	No identification obtained. (b) (4) was unable to obtain growth after isolating the organism	Microbiologist concluded the root cause was lapse in aseptic techniques.	September 6, 2025	August 25, 2025 Impacted batches (b) (4) (b) (4)
2	April 3, 2025	ISO 5 laminar flow hood (LFH)	EML_INV0000863	3CFU Count Action Limit Passive air environmental monitoring (EM)	Penicillium Sp.	Plate mishandling	May 29 2025	May 20,2025

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Ucheabuchi C Chudi-Nwankwor, Investigator

Ucheabuchi C Chudi-Nwankwor
Investigator
Signed By: Ucheabuchi C. Chudi-
nwankwor-8
Date signed: 02-17-2026
12:07:30

X

DATE ISSUED

2/17/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION																
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772					DATE(S) OF INSPECTION 2/9/2026-2/17/2026*											
					FEI NUMBER 3011121261											
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Anna K. Wierzbicki, Pharmacy Manager																
FIRM NAME PETNET Solutions Inc				STREET ADDRESS 11100 Euclid Ave Rm S-106a												
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716				TYPE ESTABLISHMENT INSPECTED PET Drug Product Manufacturer												
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 5%; text-align: center; vertical-align: top;">3.</td> <td style="width: 15%; text-align: center; vertical-align: top;">May 15, 2025</td> <td style="width: 15%; text-align: center; vertical-align: top;">ISO 5 PEC HC (b) (4)</td> <td style="width: 15%; text-align: center; vertical-align: top;">EMH_INV0000991</td> <td style="width: 15%; text-align: center; vertical-align: top;">13 CFU Count Action limit Surface contact environmental monitoring (EM).</td> <td style="width: 20%; text-align: center; vertical-align: top;"> Staphylococcus aureus, Micrococcus luteus, Staphylococcus Warneri, Staphylococcus epidermis, Moraxella osloensis, Peribacillus frigoritolerans, Peribacillus butanolivorans Staphylococcus hominis </td> <td style="width: 10%; text-align: center; vertical-align: top;">Plate Mishandling</td> <td style="width: 10%; text-align: center; vertical-align: top;">August 13, 2025</td> <td style="width: 10%; text-align: center; vertical-align: top;">June 20, 2025</td> </tr> </table>								3.	May 15, 2025	ISO 5 PEC HC (b) (4)	EMH_INV0000991	13 CFU Count Action limit Surface contact environmental monitoring (EM).	Staphylococcus aureus, Micrococcus luteus, Staphylococcus Warneri, Staphylococcus epidermis, Moraxella osloensis, Peribacillus frigoritolerans, Peribacillus butanolivorans Staphylococcus hominis	Plate Mishandling	August 13, 2025	June 20, 2025
3.	May 15, 2025	ISO 5 PEC HC (b) (4)	EMH_INV0000991	13 CFU Count Action limit Surface contact environmental monitoring (EM).	Staphylococcus aureus, Micrococcus luteus, Staphylococcus Warneri, Staphylococcus epidermis, Moraxella osloensis, Peribacillus frigoritolerans, Peribacillus butanolivorans Staphylococcus hominis	Plate Mishandling	August 13, 2025	June 20, 2025								
After the remediation, there were no documentation that these areas were resampled to verify the effectiveness of the cleaning process in mitigating the presence of these objectionable recovered microorganism. On February 10, 2025, your Regional Quality Manager stated that there is no additional re-sampling of the ISO surfaces after these remediation cleaning except for the routine (b) (4) environmental sampling. In addition, there continues to be recoveries of objectionable micro-organism in your IO 5 PEC Hot Cell even after the sporicidal cleaning. For example, following the sporicidal cleaning remediation of the ISO 5 PEC Hot Cell-(b) (4) on June 23, 2025, there was another recovery of actionable objectionable microorganisms in the ISO 5 PEC Hot Cell-(b) (4) on 7/5/2025.																
OBSERVATION 2																
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator				Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor-S Date Signed: 02-17-2026 12:07:30 X										
						DATE ISSUED 2/17/2026										

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 2/9/2026-2/17/2026* FEI NUMBER 3011121261
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anna K. Wierzbicki, Pharmacy Manager

FIRM NAME PETNET Solutions Inc	STREET ADDRESS 11100 Euclid Ave Rm S-106a
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716	TYPE ESTABLISHMENT INSPECTED PET Drug Product Manufacturer

You did not implement procedures to ensure that all equipment is 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,

- A. Your procedure D0013730, Installation Qualification (IQ) and Operational qualification (OQ) for incubators Revision D, effective 12/02/2024 to 02/01/2026 was deficient due to not performing temperature mapping which is heat distribution pattern studies as part of the operation qualification of the following equipment:

- i. (b) (4) °C Incubator (b) (4) Model (b) (4), Serial Number (b) (4)
- ii. (b) (4) °C Incubator (b) (4) Model (b) (4), Serial Number (b) (4)
- iii. (b) (4) °C Incubator (b) (4) Model (b) (4), Serial Number (b) (4)

You failed to conduct a full Installation, Operational and Performance Qualification (IQ, OQ & PQ) to include temperature mapping studies and heat distribution pattern in these incubators. These incubators were routinely utilized by your firm for the incubation of all Pet Finished Drug Product Sterility samples and Environmental monitoring plates from January 1 2024 to February 2, 2026.

- B. There is a design flaw in your ISO 5 Laminar Flow Hood (LFH) room in that the HVAC air outlet is directly located approximately less than one (1) foot above the roof of the ISO 5 LFH. In addition, the HVAC air outlet is situated in a position that air flows into the ISO 5 LFH which is located in the unclassified room. All Finished Product Vials are sterile assembled in the ISO 5 LFH and are used in the final production process of your PET drug products to include (b) (4) drug products.
- C. You failed to establish procedures to ensure continuous pressure monitoring and particulate monitoring are performed during the critical operations in ISO 5 areas to include LFH ISO 5 hood where Finished Product vials are assembled. You have produced and released approximately (b) (4) batches of finished Pet drug products to include (b) (4) batch #(b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi- nwankwor-S Date signed: 02-17-2026 12:07:30 X	DATE ISSUED 2/17/2026

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 2/9/2026-2/17/2026* FEI NUMBER 3011121261
---	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anna K. Wierzbicki, Pharmacy Manager

FIRM NAME PETNET Solutions Inc	STREET ADDRESS 11100 Euclid Ave Rm S-106a
CITY, STATE, ZIP CODE, COUNTRY Cleveland, OH 44106-1716	TYPE ESTABLISHMENT INSPECTED PET Drug Product Manufacturer

OBSERVATION 3

Your process controls did not include control of in-process materials to ensure that the materials are controlled until required tests or other verification activities have been completed or necessary approvals are received and documented.

Specifically, you do not have an in-process check on the (b) (4) target material for radioactive content. This material is returned to you as reprocessed product from all your domestic sites for re-use in your PET drug product manufacturing processes. (b) (4) batch (b) (4) used (b) (4) part No (b) (4) Lot Number (b) (4) for its manufacturing process and was released by your Quality unit on August-20-2025.

OBSERVATION 4

The RDRC did not assure that the investigator utilized adequate instrumentation for the detection and measurement of the specific radionuclide.

Specifically, you failed to qualify your (b) (4) oven operating temperature range to (b) (4) ° C. Your current Equipment Installation and Operational Qualification Report for (b) (4) dated December 22, 2023, was qualified between the temperature ranges of (b) (4) ° C to (b) (4) ° C to (b) (4) ° C - (b) (4) ° C. This does not support most analysis which requires (b) (4) ° C oven temperature.

***DATES OF INSPECTION**

2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/13/2026(Fri), 2/17/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwankwor, Investigator	Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi- nwankwor - S Date Signed: 02-17-2026 12:07:30 X	DATE ISSUED 2/17/2026

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."