

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		DATE(S) OF INSPECTION 3/17/2026-3/19/2026 FEI NUMBER 3008769593			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Scott Ruzich, Regional Director Operations - NE					
FIRM NAME PETNET Solutions Inc		STREET ADDRESS 2231 4th Ave S			
CITY, STATE, ZIP CODE, COUNTRY Birmingham, AL 35233-2307		TYPE ESTABLISHMENT INSPECTED 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: LABORATORY CONTROL SYSTEM					
OBSERVATION 1 Each laboratory used to conduct testing of finished PET drug products does not follow written procedures for the conduct of each test. Specifically, Your firm failed to follow established incubation procedures for sterility testing and environmental monitoring. A.) Your firm's procedure, Product Testing: Sterility Test (Doc# D0001993, Revision U, effective date: 09/05/2025), specifies a (b)(4) incubation period for sterility test samples. However, sterility test samples for the following batches were inspected and results recorded before completing the required (b)(4) incubation period (incubation periods ranged from more than (b)(4) to less than (b)(4)): (b)(4) Injection, Batch# (b)(4) (b)(4) Injection, Batch# (b)(4) (b)(4) Injection, Batch# (b)(4) B.) Your firm's procedure, Microbiological Environmental Monitoring of the ISO 5 Area of the Hot Cell (Doc# D0012139, Revision I, effective date: 11/01/2020), requires (b)(4) plates					
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Lillian S Wu, Investigator Youkeun Kim, Investigator </td> <td style="width: 40%; border: none; vertical-align: top;"> DATE ISSUED 3/19/2026 Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 03-19-2026 10:30:42 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Lillian S Wu, Investigator Youkeun Kim, Investigator	DATE ISSUED 3/19/2026 Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 03-19-2026 10:30:42 X
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to be incubated at (b)(4) for no less than (b)(4) then at (b)(4) for no less than (b)(4)
(b)(4) However, environmental monitoring plate SN- (b)(4) was removed from the
high-temperature incubator after (b)(4) before completing the required (b)(4)
incubation period.

X Lillian S Wu
Investigator
Signed By: 2003443287
Date Signed: 03-19-2026 10:31:14

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lillian S Wu, Investigator Yukeun Kim, Investigator	Youkeun Kim Investigator Signed By: 2002027774 Date Signed: 03-19-2026 10:30:42 X	DATE ISSUED 3/19/2026

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."