

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 3/17/2026-3/19/2026 FEI NUMBER 3031057987	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Melinda C. O'Rourke, Owner			
FIRM NAME PReye LLC		STREET ADDRESS 4855 Ward Rd.	
CITY, STATE, ZIP CODE, COUNTRY Wheat Ridge, CO 80401-8000		TYPE ESTABLISHMENT INSPECTED Repackager/Relabeler	
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 Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products. Specifically, A. Your firm repackages sterile (b) (4) drug product (b) (4), in an unclassified office environment using a (b) (4) laminar airflow hood. The area lacks appropriate cleanroom classifications (e.g., ISO 5 conditions), and your firm has not demonstrated that aseptic conditions are maintained during processing. Further, the laminar airflow hood used during repackaging has not been qualified, certified, or routinely maintained. Your firm has no documentation demonstrating that the hood provides adequate HEPA filtration or unidirectional airflow. B. Your firm does not perform viable or non-viable environmental monitoring, surface sampling, or personnel monitoring in areas where sterile drug products are repackaged. Your firm lacks data to demonstrate control of the aseptic processing environment. These conditions create a significant risk of contamination of drug products intended to be sterile.			
OBSERVATION 2 Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brittny C Cargo, Investigator		DATE ISSUED 3/19/2026
		Brittny C Cargo Investigator X Date Signed: 03-19-2026 17:36:21	

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Melinda C. O'Rourke, Owner

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Specifically,

Your firm manufactures and distributes OTC sterile drug product (b) (4) with active ingredients not permitted under OTC Monograph M018.

As a result, your firm has not ensured that drug products released for distribution meet appropriate standards of identity, strength, quality, and purity.

OBSERVATION 3

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

Your firm receives sterile drug product, (b) (4), from a compounding pharmacy and repackages them without performing identity testing. Your firm also fails to obtain or review Certificate of Analysis (COAs) to verify the identity, strength, quality, and purity of the received drug products.

OBSERVATION 4

There is no quality control unit.

Specifically,

Your firm has not been effective in carrying out its duties of ensuring drug product purported to be sterile are manufactured in accordance with current good manufacturing practices (cGMP) to ensure safety, efficacy, purity, and overall quality at your firm. This is evident by the following deficiencies:

A. Failure to qualify the following vendors:

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- Compounding pharmacy responsible for manufacturing your finished drug product, (b) (4) . In addition, the firm did not establish a quality agreement.
- (b) (4) supplier used as final packaging for (b) (4)
- (b) (4) supplier used to fill the (b) (4) for (b) (4)

B. Failure to establish procedures to conduct the following quality system processes:

- Responsibilities of the quality unit
- Repackaging of Sterile drug products
- Deviations
- Change Controls
- Customer Complaints
- Recalls
- Receipt of Materials
- Cleaning and Sanitization
- Equipment Qualification
- Supplier Qualification
- Annual Product Reviews
- Lot coding system
- cGMP training

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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."