

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661		DATE(S) OF INSPECTION 5/4/2026-5/8/2026 FEI NUMBER 2450054	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jenny R. Laws, Quality Director			
FIRM NAME Perrigo New York, Inc.		STREET ADDRESS 1700 Bathgate Ave	
CITY, STATE, ZIP CODE, COUNTRY Bronx, NY 10457-7512		TYPE ESTABLISHMENT INSPECTED 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 Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product. Specifically, You do not ensure continuous control of air pressure differential in your facility. For example: a) In your Building (b) (4) multiproduct drug manufacturing facility, you do not monitor pressure differential between compounding suites used for open process drug manufacturing and the common corridor to demonstrate directional air flow. Furthermore, you do not demonstrate continuous control over facility room pressures in accordance with your designed pressure cascade requirements. For example: On 05/04/2026 in suite (b) (4), we observed open material addition of (b) (4) ingredients for manufacture of (b) (4) Gel, (b) (4) lot # (b) (4), manufactured (b) (4). You have no indication of pressure control for the room in relation to the common corridor. b) You do not have continuous monitoring systems to ensure operation of your Building (b) (4) multiproduct drug manufacturing facility HVAC air handling units (AHUs). Furthermore, you do not document daily operational checks of AHU (b) (4) servicing manufacturing suites (b) (4)			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Ifechimere I Okafor, Investigator Edmund F Mrak, Investigator	
		DATE ISSUED 5/8/2026	
		Ifechimere I Okafor Investigator Signed By: IFECHIMERE OKAFOR 4 Date Signed: 05-08-2026 18:12:58	

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(b) (4), and (b) (4); AHU (b) (4) servicing the common corridor; and AHU (b) (4) servicing the suppository suite.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically,

- a) On 05/04/2026, in your Building (b) (4) multiproduct drug manufacturing facility we observed employees in suite (b) (4) engaged in material addition of (b) (4) ingredients for manufacture of (b) (4) Gel, (b) (4) lot # (b) (4), manufactured (b) (4). Operators in contact with raw material (b) (4) were observed leaving the room without decontamination or removal of soiled gowning components. We also observed that one employee engaged in the material addition process had modified their gowning by removing the integrated shoe covers exposing their plant footwear to raw material residues. We observed the employee leave the compounding suite and enter the common corridor without decontaminating or removing their soiled gowning components.
- b) You do not have procedures detailing proper gowning of employees engaged in open drug processing to prevent contamination of your multiproduct manufacturing facility. Furthermore, you do not have procedures for decontamination and degowning of employees before leaving the compounding suite and entering the common corridor.

OBSERVATION 3

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Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

You do not protect cleaned drug product contact equipment from contamination in accordance with your procedure, SOP-000041556, *Cleaning and Sanitizing Procedure for Major Manufacturing Equipment* which requires clean and dry equipment to be covered. For example:

- a) During inspection of Building (b) (4), suite (b) (4) on 05/04/2026 we observed the Manufacturing Kettle (b) (4), documented in clean status, was uncovered with the lid open. The tank was designated for manufacture of (b) (4) Spray (b) (4), batch # (b) (4).
- b) During inspection of the Building (b) (4) equipment storage room on 05/04/2026, we observed Pump (b) (4) ((b) (4)) documented in clean status uncovered with product contact areas exposed. Pump (b) (4) ((b) (4)) is used for drug products including (b) (4) Lotion, lot # (b) (4) manufactured on (b) (4).

OBSERVATION 4

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically,

We observed the following objectionable facilities conditions in your Building (b) (4) multiproduct drug manufacturing facility:

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- a) On 05/04/2026, during inspection of compounding suites in Building (b) (4), we observed multiple cracks and delamination of epoxy floor surfaces. For example,
- i. In suite (b) (4), we observed cracking and delamination of a previous repair in an area approximately 3x2 ft on the epoxy floor surface. The room was designated for manufacture of (b) (4) Spray (b) (4), batch # (b) (4)
 - ii. In suite (b) (4), we observed cracking and delamination of the floor and standing liquid in an area approximately 3x2 ft. At the time of this observation, we observed that an employee was assembling the (b) (4) valve on (b) (4) Kettle W/ Mixer (b) (4) in close proximity to the damaged area. The tank was designated for production of (b) (4) Spray (b) (4), batch # (b) (4).
 - iii. In idle suite (b) (4), we observed cracking and delamination of the floor in an area approximately 1x1 ft adjacent to the room floor drain. According to the equipment log, Manufacturing Kettle (b) (4) Mixer ((b) (4)) is used for drug products including (b) (4) Ointment, (b) (4), batch # (b) (4), manufactured (b) (4).
- b) In Building (b) (4), suite (b) (4), we observed that a ceiling tile with hoist chain passed through it located above the Manufacturing Kettle (b) (4) was dislodged and open to the uncontrolled area above the ceiling. The Manufacturing Kettle (b) (4) was observed open and uncovered. The kettle was designated for manufacture of (b) (4) Spray (b) (4), batch # (b) (4).

Edmund F Mrak
Investigator
Signed By: EDMUND F. MRAK JR -S
Date Signed: 05-08-2026 18:13:33
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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."