DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	6/1/2026-6/5/2026
	FEI NUMBER 3033529550

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samantha L Zeller, Program Manager

FIRM NAME	STREET ADDRESS
My CHS Rx, Inc.	70 Arkay Dr Ste 12
CITY, STATE, ZIP CODE, COUNTRY Hauppauge, NY 11788-3708	TYPE ESTABLISHMENT INSPECTED Drug Repackager and Relabeller

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

There is no quality control unit.

Specifically,

You failed to establish and maintain a Quality Unit (QU) capable of effectively implementing a Current Good Manufacturing Practice (CGMP)- compliant quality system. For example:

A. Current quality functions are performed by a single off-site Quality Assurance (QA) employee who is not involved in day-to-day operations and whose role is limited to the maintenance of policies.

B. Existing policies do not provide sufficient step by step details of their intended processes to effectively guide operations. Such as but not limited to:
   1.Quality Review
   2.Batch production Record
   3.Corrective and Preventative Action (CAPA)
   4.Incident Reporting
   5.Equipment Cleaning and management
   6.Label control
   7.Deviation Management

C. There is no documented evidence that QU has ensured adherence to these policies, as there are no records of QU reviews of work performed at your facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Luxuly Abraham, Investigator X Luxuly Abraham Investigator Signed By: 2004171406 Date Signed: 06-05-2026 16:42:56	6/5/2026

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OBSERVATION 2

Employees are not given training in current good manufacturing practices.

Specifically,

You failed to establish and implement a CGMP training program for employees engaged in the packaging, labeling, and holding of drug products. Your Training Policy, Revision 1, effective December 10, 2025, does not address CGMP training requirements, nor have job-specific training records been maintained for your employees as required by your own policy. No training records, written training procedures or programs, or documented evidence of completed training were available during the inspection to demonstrate that personnel had been trained on applicable CGMP regulations or policies relevant to their assigned functions.

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

You failed to establish procedures and conduct equipment qualifications (IQ, OQ, PQ) for the equipment listed below. Additionally, you failed to establish and implement adequate procedures governing equipment identification, calibrations, calibration records, and maintenance of equipment used at your firm to include:

- (b) (4) Model : (b) (4) ,Serial : (b) (4)
- (b) (4) , Model: (b) (4) ,Serial: (b) (4)

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☐**Pill Counter,** Model : (b) (4),Serial : (b) (4)

Currently this equipment is used for the packaging and relabeling of products such as but not limited to: (b) (4), (b) (4), (b) (4) and (b) (4).

OBSERVATION 4

Procedures designed to assure that correct labels, labeling and packaging materials are used for drug products are not written and followed.

Specifically,

You failed to conduct a process validation to assure the suitability of the packaging and labeling processes to ensure that the (b) (4) Packaging Paper used in the (b) (4) (b) (4) packaging system is suitable for your specific products and packaging operations. Your firm transfers drug products from their original manufacturer containers and repackages them into (b) (4) using the (b) (4) Packaging Paper; however, there is no documented evidence that this packaging material was examined or tested by your firm to confirm its compatible for use with the drug products being repackaged. Also, you have not established the reliability of the packaging process to ensure integrity of the (b) (4) and durability of labeling under transport and storage conditions. Currently you repackage and relabel drug products such as but not limited to:

a. (b) (4) USP
b. (b) (4)
c. (b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Luxuly Abraham, Investigator

X Luxuly Abraham
Investigator
Signed By: 2004171406
Date Signed: 06-05-2026
16:42:56

DATE ISSUED
6/5/2026

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."