DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/11/2025-8/14/2025
	FEI NUMBER 3004086743

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew P Wyse, Senior Pharmacist

FIRM NAME	STREET ADDRESS
University Of Pittsburgh Medical Center Centralized Packaging	3175 E Carson St Rm 131
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pittsburgh, PA 15203-2130	Drug repackager

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

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically,

You failed to conduct a cleaning validation study to demonstrate that your cleaning procedures effectively remove penicillin residues from equipment that is used to repackage both penicillin and non-penicillin drug products.

(A) From June 2023 to August 14, 2025, Bulk (b)(4) Packager, Bulk (b)(4) Packager, Bulk (b)(4) Packager, Bulk (b)(4) Packager, and Bulk (b)(4) Packager were used to repackage approximately (b) (4) solid oral doses of drug products, of which approximately (b) (4) doses involved penicillin products. Your cleaning procedure for bulk packager was not established based on a cleaning validation study to assure effective removal of penicillin residues to prevent cross-contamination with non-penicillin drug products.

(B) From June 2023 to August 14, 2025, the (b) (4) was used to repackage (b) (4) lots of drug products, of which (b) (4) lots involved penicillin products. You did not perform a cleaning validation study to establish a detailed cleaning procedure for the (b) (4) to assure effective removal of penicillin residues to prevent cross contamination with non-penicillin drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yaharn Su, Investigator X Yaharn Su Investigator Signed By: 2004003466 Date Signed: 08-14-2025 13:36:57	8/14/2025

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OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

From August 01, 2024, to August 12, 2025, your firm identified 750 defects but did not investigate them to determine root causes. In addition, you lack adequate written procedures for investigating discrepancies to determine whether corrective action or extension of the investigation to other lots is required. For example:

(A) Defect ID 11880 identified a discrepancy regarding a unit dose that was distributed to a hospital containing two different tablets.

(B) Ten defects identified as having "foreign particle packaged" were not investigated to determine the source of the contaminant. These include Defect ID: 11510, 11511, 11619, 11680, 11839, 12126, 12171, 12183, 12202, 12203.

OBSERVATION 3

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

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Your firm repackages (b) (4) dosage forms into (b) (4) containers and assigns an expiration date of the (b) (4) without conducting supporting stability studies. For example:

- (b) (4) per tablet, lot (b) (4), repackaged on 07/25/2025 was assigned an expiration date of (b) (4).
- (b) (4) capsule, lot (b) (4), repackaged on 07/30/2025 was assigned an expiration date of (b) (4).

(Repeat observation from previous inspection ended on 06/05/2009)

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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."