DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115 oradevices2firmresponse@fda.hhs.gov	6/12/2023-6/20/2023* FEI NUMBER 3004453700

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tiffany N. Welborn, Quality Assurance Manager

FIRM NAME	STREET ADDRESS
Legacy Pharmaceutical Packaging LLC	13333 Lakefront Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Earth City, MO 63045-1514	Medical Device Repacker / 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been established.

Specifically, Legacy Pharmaceutical Packaging is the manufacturer of (b) (4) . The (b) (4) are an FDA class 3 medical device for the detection of (b) (4) .

From May 2021 thru March 2023, the following complaints were received which reported missing components in the (b) (4):

Row	Date	Complaint ID	Lot number	Component(s) Missing
1	5/18/2021	2021-0265	(b) (4)	
2	7/14/2021	2021-0370		
3	7/14/2021	2021-0371		
4	11/29/2021	2021-0715		
5	4/25/2022	2022-0206		
6	8/1/2022	2022-0399		

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EMPLOYEE(S) SIGNATURE
Edward E Lockwood, Investigator

X Edward E Lockwood
Investigator
Signed By: Edward E. Lockwood - S
Date Signed: 06-20-2023 14:08:33

DATE ISSUED
6/20/2023

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7	11/29/2022	2022-0639	(b) (4)
8	3/1/2023	2023-0092	

(b) (4)

Per the master batch record, document # MBR-(b) (4) all missing components listed in the complaints above are classified as critical defects.

All eight (8) complaints, read in part:

"Corrective and Preventive Action:

****An action item AI-0347 was previously initiated for a similar complaint in Legacy's Quality Management System to conduct training to make packaging personnel aware of complaint and ensure that the requirements of instructions provided in the MBR are understood and followed by all applicable personnel****."*

There are no written procedures for action items (AI). Per AI-0347, this action item was implemented on or about 8/5/2021 and completed on or about 2/7/2023.

This corrective action (Action Item AI-0347) was not in accordance with Legacy Pharmaceutical Packaging's CAPA SOP-0242. For example, action item AI-0347:

i. does not document root cause analysis
ii. does not document management's approval
iii. does not document effectiveness checks (planned or actual)
iv. was not completed in (b) (4) or if an extension was requested/approved

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OBSERVATION 2

Software used as part of the quality system has not been adequately validated for its intended use according to an established protocol.

Specifically, Legacy Pharmaceutical Packaging's (LPP) Validation Master Plan (VMP), POL-0013, Rev 00, reads in part:

> "*8.0 Computer related systems at LPP****
>
> *8.2.1 Computer systems utilized in the packaging, control or testing of regulated products and /or raw materials (including packaging components or labeling) that impact the overall quality, safety or efficacy of the products or related data will be validated in accordance to this VMP*"

On or about 1/11/2022, a Legacy Pharmaceutical final release quality inspection identified that the shipping carton label UDI (unique device identifier) QR (quick response) code was incorrect for (b) (4), lot (b) (4). The human readable version of the UDI was correct. As a result of this nonconformance, (b) (4) shippers (containing (b) (4) cartons) were relabeled. The cause of the labeling nonconformance was reported as human error when creating the UDI labels using the labeling software.

Per QP 11-015, the labeling software was validated on or about 07/11/2011 for version 5.11.1.1500. The validation protocol's objective reads in part:

> "*The XXX software is used to create labels and database for the bundle and shipper labels used at Legacy Pharmaceutical Packaging. This protocol will verify that the label printers will consistently and correctly print bundle and shipper labels created and stored in the XXX database.****""

The validation accomplished in 2011 did not include documentation that any labeling with QR codes were included in the validation.

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The currently version of the labeling software is (b) (4) . There is no documentation the labeling software has been validated since 2011.

***DATES OF INSPECTION**

6/12/2023(Mon), 6/13/2023(Tue), 6/14/2023(Wed), 6/16/2023(Fri), 6/20/2023(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."