DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	01/13/2020-01/16/2020* FEI NUMBER 3004453700

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Cory G. Robinson, Director of Quality / Regulatory Affairs

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

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

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the following was noted from review of the *Final Report for Performance Qualification for Packaging* (b) (4), dated on or about 12/23/19:

A. The process control verification protocol (QP 19-416,-417 and -418, part 8.0) documents the Vision System Challenge tests for incorrect/illegible carton part code and /or UDI barcode on the carton label was a critical quality classification. The final report (part 4.0) reads as follows: "******All PQ tests of the *** Vision System with *** camera and critical quality attribute checks were performed, verified and demonstrated to meet all acceptance criteria*****".

   i. However, the vision system challenge, as described in part 9 of the (b) (4) packaging instructions (Document Number MBR-0602, revision 01), does not include using a challenge carton with either an incorrect carton part code or incorrect UDI barcode. The packaging project manager stated the optical character recognition (OCR) capability of the vision system was never tested (challenged) to detect and reject incorrect part codes or incorrect UDI bar codes during any of the (b) (4) performance qualification (PQ) lots.

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ii. He said the vision system was challenged for missing / illegible codes, only. The challenge devices for missing / illegible codes were not a controlled/standardized set of test articles used for all performance qualification (PQ) lot tests. The test articles were (b) (4) to each challenge of each lot (b) (4) vision challenges were performed per lot).

B. The final report (part 5.0) reads as follows: "*There were no exceptions initiated during the execution of the PQ protocols*". However the following occurred and were not included in the final PQ evaluation:

i. Maintenance was required to adjust the vision system during (b) (4) production lot number (b) (4). The engineering technician said he adjusted (b) (4) on the vision system because the system was rejecting too many packages. This maintenance activity was not documented or evaluated as a process exception in the final report.

ii. Vision system labeling rejects was a stated critical quality attribute check for the performance qualification, however the number of labeling rejects (nonconformances) detected were not recorded or evaluated as process exceptions in the final report.

iii. The packaging project manager stated rejected/mislabeled cartons were reworked during (b) (4) of the production lots. However, the amount of rework was not recorded or included the final report as a process exceptions.

OBSERVATION 2

Rework and reevaluation activities have not been documented in the device history record.

Specifically, the packaging project manager said mislabeled packages were rejected in (b) (4) performance qualification production lots. He said the contents (b) (4)) were removed from the rejected cartons and reused. The mislabeled packages were destroyed.

There was no documentation in the device history records for the (b) (4) performance qualification lots of any rework or reevaluation of the rejected package components. Lot numbers for the performance qualifications were (b) (4).

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OBSERVATION 3

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically, the vision system is intended to detect and reject packages for lot numbers and bar codes that are either missing or inaccurate. The packaging project manager stated the optical system detected failures (rejects) of labeling non-conformances during production of (b) (4) of the performance qualification lots. The number of labeling rejections (nonconformances) detected during the PQ production runs were not recorded.

A. There were no reports documenting the identification, documentation, evaluation, segregation, and disposition of nonconforming products.

B. There was no documentation of an evaluation of nonconformance to include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.

OBSERVATION 4

Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established.

Specifically, maintenance activities, including the reason (problem), maintenance performed, date and individual(s) performing the maintenance activities, were not documented when maintenance was accomplished on the vision system for performance qualification lot number (b) (4)

OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

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Specifically, Legacy does not have complaint procedures that ensure complaints are evaluated for MDR reportability.

***DATES OF INSPECTION**
1/13/2020(Mon), 1/14/2020(Tue), 1/16/2020(Thu)

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: 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."