DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772	6/8/2026-6/12/2026
	FEI NUMBER 3008841077

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark D. Saxon, CEO

FIRM NAME	STREET ADDRESS
Safecor Health, LLC	4060 Business Park Dr Ste B
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43204-5047	TYPE ESTABLISHMENT INSPECTED Repackager/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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm does not perform investigations for reprocessed batches. Your firms reprocessing procedure, SOP WI-082, Reprocessing Packaged Drugs, effective date 06/20/2024, Rev. B, specifically calls out that deviations are not required for reprocessed batches, indicating that investigations would not be performed. When actions are taken, they are limited to immediate corrective measures, such as operator coaching, without a documented evaluation of the underlying cause. For example,

A. Batch (b) (4) of (b) (4) Tablets was reprocessed due to improperly sealed foil pouches; however, no investigation was conducted to determine whether the failure resulted from operator error, equipment malfunction, inadequate process controls, or another assignable cause. Additionally, quality personnel documented the reason for reprocessing as a sealing failure, while the operator documented the reason as a labeling issue on the in-process deviation form. The discrepancy was neither investigated nor reconciled, and the batch record does not establish the actual reason for reprocessing.

B. Batch (b) (4) of (b) (4) Tablets was reprocessed due to improperly sealed foil pouches. No investigation was conducted to determine whether the failure resulted from operator error, equipment malfunction, inadequate process controls, or another assignable cause. Your firm lacks assurance that appropriate corrective and preventive actions have been

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Anna M Spiros, Investigator	X Anna M Spiros Investigator Signed By: 2004340890 Date Signed: 06-12-2026 11:36:20	6/12/2026

implemented to prevent recurrence of similar failures.

C. Batch (b) (4) of product (b) (4) was reprocessed due to labeling defects and leaking (b) (4); however, the quantity of units affected by each defect was not recorded. There was no investigation performed as to the cause of the leaking (b) (4) and the batch record does not adequately identify the extent of each defect or reconcile the affected units.

Furthermore, your firm does not track and trend these events to identify recurring failure modes, assess whether systemic issues are contributing to repeated occurrences, or implement corrective actions. Your firm has reprocessed approximately (b) (4) batches since June of 2024 without adequate tracking, trending, or investigations.

OBSERVATION 2

Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically, batch production and control records are not generated for each reprocessing event, and existing reprocessing records are incomplete and inaccurate. Examples include, but are not limited to:

A. During reprocessing of Batch (b) (4) of (b) (4), labels and overwraps were discarded; however, no secondary accountability form was generated as required by procedure, WI-082, Reprocessing Packaged Drugs, effective date 06/20/2024, Rev. B. Instead, the discarded components were documented on the original accountability form, leaving component disposition and reconciliation inadequately documented.

B. Packaging and labeling component accountability records for batch (b) (4) of(b) (4)

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(b) (4) contained discrepancies and calculations that firm personnel were unable to explain during the inspection. As a result, the accuracy and completeness of component accountability could not be verified.

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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."