DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/16/2026-3/20/2026
	FEI NUMBER 1818658

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ramneek Ashok, Director of Regulatory Management and Compliance

FIRM NAME	STREET ADDRESS
The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	341 Mason Rd
CITY, STATE, ZIP CODE, COUNTRY La Vergne, TN 37086-3606	TYPE ESTABLISHMENT INSPECTED Own Label Distributor/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 WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, your firm's written procedure SOP-05162, "Repackager Authorization to Ship," effective date December 8, 2025, is inadequate because it does not establish that the quality unit must review and verify the accuracy of variable data printed on finished drug product labels prior to release and authorization to ship. The procedure fails to require your quality unit verification of critical variable data including, but not limited to, lot number and expiration date, against the information reported on the Certificate of Compliance (CoC).

Examples include, but are not limited to, your quality unit authorized release of:

a. (b) (4) Capsules, USP (b) (4) mg, lot (b) (4) expiration date (b) (4) The signed associated Certificate of Compliance lacks documentation demonstrating that the quality unit verified the accuracy of variable data (lot number and expiration date) printed on the finished product labels against the CoC specifications.

b. (b) (4) Tablet, USP (b) (4) g, lot (b) (4) expiration date (b) (4) The associated signed Certificate of Compliance lacks documentation demonstrating that the quality unit verified the accuracy of variable data (lot number and expiration date) printed on the finished product labels against the CoC specifications.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Demario L Walls, Investigator Nelson N Ayangho, Investigator Sarah E Venti, FDA Center Employee	X	3/20/2026

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OBSERVATION 2

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

Your firm failed to expand investigation SCAR-000303 dated December 30,2025 to other lots after the root cause was identified as using a defective sealing process and material. Your firm received more 20 complaints between December 12, 2025, to March 3, 2026, reporting a similar inadequate blister seal strength for (b) (4) Tablets, USP, (b) (4) mg.

The investigation only focused on (b) (4) Tablets, USP (b) (4) mg, Lot (b) (4) expiration date (b) (4) and ultimately led to a recall. However, the same process and materials were used across multiple lots and multiple products including but not limited to,

Product Name	Major NDC # (b) (4)	Repackaged Lot #	# Saleable Units	Date Released	Expiration Date
[redacted]					

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(b) (4)

[redacted]

Each lot listed was approved and released for distribution by your firm's quality unit.

OBSERVATION 3

Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA.

Specifically, your SOPs #04886, CAHPPL - Complaint Processing in Vault, effective October 21, 2025,

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#04678, Discovery and Reporting of Suspected Counterfeit Product, effective January 26, 2026, and #05089, Drug Supply Chain Security Act Product Verification and Notification, version 2, which apply to Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories' (Harvard) operation as a private label distributor, do not establish adequate systems and processes for:

A. Identifying and investigating suspect product before the product reaches Harvard's distribution center located at (b) (4)

B. Responding to notifications of illegitimate product from FDA or a trading partner.

X _____ X _____

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