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	12/10/2024-12/12/2024
	FEI NUMBER 1025513

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dawn M. Boyter, CEO

FIRM NAME	STREET ADDRESS
Richie Pharmacal Company, Inc.	119 State Avenue
CITY, STATE, ZIP CODE, COUNTRY Glasgow, Kentucky 42141	TYPE ESTABLISHMENT INSPECTED Wholesale Distributor

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

Your firm does not have adequate systems and processes to enable compliance with the verification requirements of section 582(c) of the Drug Supply Chain Security Act (DSCSA).

Specifically,

A. Your firm's unsigned written procedure SOP 7.19, "Suspect and Illegitimate Product," created 7-19-17, is inadequate in that it fails to describe systems and processes (1) to terminate a notification of illegitimate product in consultation with FDA and the SOP includes an invalid hyperlink to FDA Form 3911 on FDA's website for FDA Form 3911; (2) to identify suspect product; (3) to conduct investigations of suspect product in coordination with trading partners, which must include verifying the product identifier at the package level; and (4) to notify FDA, when applicable, that suspect product is not illegitimate product. Your firm's unsigned written procedure SOP 3.11, "Receiving Instructions," revised 3-11-24, incorrectly states that disposition of product will be authorized by the board of pharmacy and the FDA. The DSCSA requires that firms disposition illegitimate product.

B. Your firm lacks training programs to ensure that the systems and processes for verification are followed, nor maintains the training records for employees trained on receiving and identifying suspect and illegitimate products.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	S. Paranthaman Brandy Edmonds	Paranthaman Senthamarai Kannan, Investigator Brandy Edmonds Regulatory Counsel	12/12/2024

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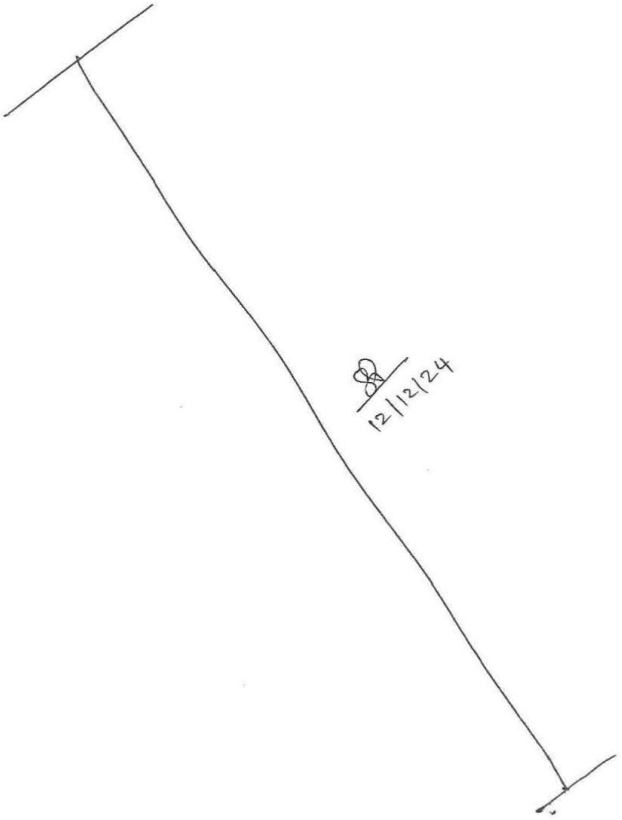
C. The firm's SOPs titled including but not limited to, "Receiving instructions, SOP 3.11, Warehousing and shipping SOP 3.11, Authenticating Vendors, SOP 3.11, and Suspect and illegitimate product, SOP 7.19 " do not have reviewed and approved by signatures.



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