DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Florida District Office 555 Winderley PL Maitland FL 32751 Phone: 407-475-4200 Industry Information: www.fda.gov/oc/industry	03/03/2025-03/06/2025
	FEI NUMBER 3007309337

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dean Berry, President

FIRM NAME	STREET ADDRESS
Sterling Distributors, LLC	4381 NW 124 Ave
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Coral Springs, FL 33065	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 (I) (WE) OBSERVED:

OBSERVATION 1:

From August 2024 to February 2025, your firm engaged in wholesale distribution of prescription drug products without being appropriately licensed as required by section 503(e) of the Federal Food Drug and Cosmetic Act (FD&C Act).

Your firm received (b) (4) units of prescription drug products from a vendor, Distributor A, from August 29, 2024 to February 4, 2025. Your firm sold (b) (4) units of prescription drug units to customers from August 29, 2024 to February 5, 2024. For example, your firm approved the following distributions of prescription drug productions without a Florida, (b) (4) wholesale license:

1. On 11/5/2024, distribution of (b) (4) units of (b) (4) mg Injection. (b) (4) units was a counterfeit product with lot # (b) (4) The (b) (4) unit is lot # (b) (4) (b) (4) lots were shipped under the same tracking number (b) (4) to a pharmacy in (b) (4)

2. On 12/09/2024, distribution of (b) (4) unit of (b) (4) mg Injection, lot # (b) (4) under shipment tracking number (b) (4) to a pharmacy in (b) (4)

3. On 12/10/2024, distribution of (b) (4) units of (b) (4) injection, lot numbers (b) (4) and (b) (4) units of (b) (4) mg Injection lot numbers (b) (4) under the shipment tracking number (b) (4) to a pharmacy in (b) (4)

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OBSERVATION 2:

Your firm failed to comply with the requirements of section 582(c) of the FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA). For example:

1. Your firm conducted transactions with trading partners who are not authorized trading partners in violation of section 582(c)(3) of the FD&C Act, as amended by the DSCSA. Specifically, on August 29, 2024, your firm purchased product covered by the DSCSA from another drug distributor, Distributor A. Distributor A does not hold appropriate state licensure and has not made annual reports to the FDA. In addition, by November 2024 you were made aware that this distributor may be distributing illegitimate product, and you continued to work with Distributor A until February 2025.

2. Your firm failed to respond to requests for information from federal and state regulators as required by section 582(c)(1)(C) of the FD&C Act, as amended by the DSCSA. For example, a request for records about suspected counterfeit or diverted product identified at a pharmacy in (b) (4) dated 11/19/24, sent via certified mail and delivered to Sterling Distributors at 4381 N.W. 124 Avenue, Coral Springs, FL, 33065 by the (b) (4) Board of Pharmacy was not responded to. In addition, the (b) (4) Board of Pharmacy first reached out to Sterling on or around 1/8/25, seeking information about suspected counterfeit or diverted product identified at a pharmacy in (b) (4) On 1/23/25, the (b) (4) Board of Pharmacy followed up via email and certified mail. The (b) (4) Board of Pharmacy did not receive a response from Sterling on any of the communications. Finally, when the Food and Drug Administration presented you with a Request for Information Letter on 3/4/24, you were unable to provide FDA with the applicable transaction information and transaction statement.

3. Your firm failed to respond to notifications of illegitimate product from trading partners as required by section 582(c)(4)(B)(iii) of the FD&C Act, as amended by the DSCSA. For example, your firm was notified by a dispenser that they were concerned they had received falsified (b) (4) from Sterling after product was returned to the dispenser. The manufacturer of the product determined that the product was counterfeit. The dispenser returned the product to Sterling on 12/5/24 and your firm took no action to investigate the product, identify other illegitimate product in your possession or control, including product subsequently received, and notify trading partners as required by the DSCSA. Your firm also failed to cooperate with the manufacturer's investigation into

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this product. The manufacturer first contacted your firm on 12/17/24 and followed up via voice message and email on 12/19/24 and 1/3/25. These subsequent communications were not responded to, and Sterling never addressed the manufacturer's questions about the returned product. Notably, your firm continued to receive product containing the same lot number from the same distributor, Distributor A, and your firm continued to distribute this product. Your firm continued to receive shipments of this product from Distributor A until January 28, 2024, and last distributed product containing this lot number on February 3, 2025.

4. Your firm failed to appropriately identify and investigate suspect product in your possession or control as required by section 582(c)(4)(A)(i) of the FD&C Act, as amended by the DSCSA. For example, you failed to identify as suspect product, and investigate accordingly, product distributed from a firm that you knew, or had reason to know, had been identified by a trading partner and two states boards of pharmacy as distributing suspect or illegitimate product. Your firm continued to purchase from this distributor, Distributor A, through February 4, 2024, and distribute the same lot numbers you had been alerted to by your downstream trading partner and the two state boards of pharmacy, up until February 5, 2025.

5. Your firm failed to collect and maintain transaction information and transaction statements as required by section 582(c)(1)(A) of the FD&C Act, as amended by the DSCSA. Your firm also failed to share transaction information and transaction statements with downstream trading partners as required by section 582(c)(1)(A) of the FD&C Act.

6. Your firm failed to make notifications to trading partners of illegitimate product in your possession or control as required by section 582(c)(4)(B)(ii). Specifically, after receiving a returned unit of counterfeit (b) (4) from a dispenser, your firm did not conduct an investigation in coordination with trading partners. For example, you did not verify the product identifier with the manufacturer by confirming that the product identifier upon the package corresponded to the information assigned to the product by the manufacturer.

7. Your firm failed to have systems in place to comply with the verification requirements of section 582(c)(4) of the FD&C Act, as amended by the DSCSA. For example: 1) your firm failed to have systems in place to identify suspect product; 2) your firm failed to have systems in place to conduct investigations into suspect product,

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including systems for coordination with trading partners; 3) your firm failed to have systems in place to make notifications of illegitimate product to FDA and trading partners; and (4) your firm failed to have systems in place to respond to notifications of illegitimate product.

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