WARNING LETTER

Sterling Distributors MARCS-CMS 706508 — JUNE 05, 2025

- **Warning Letters**
  - About Warning and Close-Out Letters

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Dean Berry

President

Sterling Distributors

4381 NW 124th AveCoral Springs, FL 33065-7634United States

dberry@sterlingdistributors.net

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

Warning Letter 706508

June 5, 2025

FEI: 3007309337

Dear Mr. Berry:

The U.S. Food and Drug Administration (FDA) inspected your wholesale distribution facility, Sterling Distributors (Sterling), FEI 3007309337, 4381 NW 124th Ave, Coral Springs, FL 33065-7634, from March 4, 2025, to March 6, 2025.

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. 360eee-1) specifies the requirements that certain entities in the pharmaceutical distribution supply chain (including wholesale drug distributors, as defined by the DSCSA) must follow related to product tracing, product identification, verification, and authorized trading partners. This warning letter summarizes significant violations by your firm of requirements in section 503(e) and 582(c) of the FD&C Act. These requirements are intended to help preserve the security of the supply chain for certain prescription drug products, thereby protecting patients from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

FDA issued a Form FDA 483 to Sterling at its Coral Springs, FL headquarters location on March 6, 2025. FDA reviewed Sterling's response submitted on March 26, 2025.

DSCSA Violations

During FDA's inspection, our investigators observed that your firm failed to comply with various requirements of the DSCSA. Specific violations include, but may not be limited to, the following:

1. Your firm engaged in wholesale distribution of prescription drug products without being appropriately licensed (FD&C Act Section 503(e)).

Under section 503(e)(1)(A) of the FD&C Act, no person may engage in wholesale distribution of a prescription drug unless such person is (i) licensed by the State from which the drug is distributed, or if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary, and (ii) licensed by the State into which the drug is distributed if that State requires licensure of a person that distributes drugs into the State.

Between August 29, 2024, and February 4, 2025, your firm received **(b)(4)** prescription drug products from **(b)(4)**. Between August 29, 2024, and February 5, 2025, your firm distributed these prescription drug units from its Florida facility to customers all over the U.S.

For example, your firm conducted the following distributions of prescription drug products without the required licensure in Florida, Arkansas or Mississippi in violation of section 503(e) of the FD&C Act:

- On 11/5/2024, distribution of **(b)(4)** units of **(b)(4)** with lot #s **(b)(4)**. **(b)(4)** units were shipped under the same tracking number **(b)(4)** to a pharmacy in Arkansas.
- On 12/09/2024, distribution of **(b)(4)** unit of **(b)(4)**, with lot # **(b)(4)** under shipment tracking number **(b)(4)** to a pharmacy in Arkansas.
- On 12/10/2024, distribution of **(b)(4)** units of **(b)(4)**, lot #s **(b)(4)**, and **(b)(4)** units of **(b)(4)**, lot #s **(b)(4)** under the shipment tracking number **(b)(4)** to a pharmacy in Mississippi.

Your firm was not able to demonstrate that Sterling held a prescription drug wholesale distribution license from Florida, where Sterling is located and from where Sterling distributes drugs. In addition, while both Arkansas and Mississippi require licensure of a person that distributes drugs into their states, Sterling was not licensed in either state at the time these prescription drugs were distributed to customers in these states.

2. Your firm conducted transactions with trading partners that were not authorized (FD&C Act Section 582(c)(3)).

Under section 582(c)(3) of the FD&C Act, trading partners of wholesale drug distributors must be authorized trading partners. Under section 581(2)(B) of the FD&C Act, to be authorized, a wholesale drug distributor must have a valid license under state law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act, and comply with the licensure reporting requirements of section 503(e) of the FD&C Act. Under section 503(e)(2)(A) of the FD&C Act, wholesale distributors must report to FDA, on an annual basis, "each State by which the person is licensed and the appropriate identification number of each such license; the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business;" and "any significant disciplinary actions."

Sterling purchased product from a trading partner that was not authorized. Specifically, between August 29, 2024, and February 4, 2025, your firm purchased prescription **(b)(4)**products from **(b)(4)**, another wholesale drug distributor. FDA has no record of **(b)(4)** ever submitting the required annual reports to FDA regarding state licensure as required by section 503(e) of the FD&C Act, and there is no evidence that **(b)(4)** held the appropriate state licensure. Further, Sterling could not demonstrate that it took any action to verify the licensure or reporting status of its direct trading partner, **(b)(4)**.[1]

3. Your firm failed to respond to requests for information from Federal and State Officials (FD&C Act Section 582(c)(1)(C)).

As required by section 582(c)(1)(C) of the FD&C Act, upon a request from Federal or State officials investigating a suspect product or illegitimate product, wholesale drug distributors must respond, within one (1) business day to such a request with the applicable transaction statement and transaction information for the product.

As part of its investigation into suspect or illegitimate product identified at a pharmacy in Arkansas, the Arkansas Board of Pharmacy (BoP) sent Sterling a subpoena for records, dated November 19, 2024, via certified mail commanding Sterling to produce records showing purchase information for all products Sterling sold and/or shipped into Arkansas since November 19, 2022. Sterling was not able to demonstrate that it responded to the inquiry, or that it responded to the Arkansas BoP's follow-up subpoena dated January 14, 2025. After Sterling's non-response, the Arkansas BoP suspended Sterling's Arkansas medical gas license. Sterling was notified of this decision in a February 14, 2025, letter sent via certified mail. In addition, the Mississippi BoP first reached out to Sterling via phone call on or around January 8, 2025, seeking information as part of its investigation into suspect or illegitimate product identified at a pharmacy in Mississippi. On January 23, 2025, the Mississippi BoP followed up via email and certified mail requesting invoices for any medications Sterling shipped to Mississippi since January 1, 2022. During the inspection,

Sterling acknowledged that it had been contacted by the Arkansas and Mississippi BoP. Sterling was unable to demonstrate that it responded to the Mississippi BoP.

Additionally, when FDA presented Sterling with a 582(c)(1)(C) request for information letter on March 4, 2025, your firm did not provide FDA with the applicable transaction information and transaction statement for the products subject to the request. In fact, in response to this request by FDA, you stated, by letter dated March 5, 2025, that Sterling "does not maintain such records in the ordinary course."

4. Your firm failed to identify suspect product in its possession or control (FD&C Act section 582(c)(4)(A)(i)), promptly conduct an investigation with trading partners to determine whether the suspect product was an illegitimate product (FD&C Act Section 582(c)(4)(A)(i)(II)), determine, in coordination with the manufacturer, whether product in its possession or control is illegitimate (FD&C Act Section 582(c)(4)(B)), respond to notifications of illegitimate product from trading partners (FD&C Act Section 582(c)(4)(B)(iii)), and make notifications of illegitimate product to FDA and trading partners (FD&C Act Section 582(c)(4)(B)(ii)).

Under section 582(c)(4)(A) of the FD&C Act, wholesale drug distributors must determine whether product in its possession or control is suspect product. Under section 582(c)(4)(A)(i)(II), upon making a determination that a product in its possession or control is a suspect product, a wholesale drug distributor must promptly conduct an investigation in coordination with trading partners, where applicable, to determine whether the product is an illegitimate product. This determination must be made in coordination with the product's manufacturer (see FD&C Act section 582(c)(4)(B)(i)). In addition, under section 582(c)(4)(B)(iii) of the FD&C Act, wholesale drug distributors must respond to a notification of illegitimate product from a trading partner by identifying all illegitimate product subject to the notification in the wholesale drug distributor's possession or control, including any product that is subsequently received, and performing the activities specified in section 582(c)(4)(A) of the FD&C Act, including, but not limited to, quarantining and dispositioning any product within the possession or control of the wholesale distributor. Further, under section 582(c)(4)(B)(ii) of the FD&C Act, not later than 24 hours upon determining that a product in its possession or control is an illegitimate product, a wholesale drug distributor must notify FDA, and all immediate trading partners that the wholesale drug distributor has reason to believe may have received the illegitimate product, that the product is illegitimate.

On December 4, 2024, Sterling was notified by one of its trading partners, a dispenser, that the dispenser was concerned it had received "mispackaged" **(b)(4)** from Sterling after product was returned to the dispenser by a patient. At that point, Sterling was obligated to promptly conduct the investigation specified in 582(c)(4)(A)(i)(II) of the FD&C Act; yet Sterling failed to do so. Based on photos of the returned product, the product's manufacturer, **(b)(4)**, later determined that the product was counterfeit and an illegitimate product. The product was not a genuine unit of **(b)(4)** but rather a unit of **(b)(4)** with falsified **(b)(4)** labeling. The dispenser returned the product to Sterling on December 5, 2024. This further obligated Sterling to promptly conduct the investigation specified in 582(c)(4)(A)(i)(II); yet Sterling again failed to do so. Instead, Sterling returned the product to its supplier, **(b)(4)**, without conducting its own investigation.

On December 17, 2024, **(b)(4)** contacted Sterling about the unit of **(b)(4)** with falsified **(b)(4)** labeling as a part of their investigation into the counterfeit and illegitimate

product. This again obligated Sterling to promptly conduct the investigation specified in 582(c)(4)(A)(i)(II); yet Sterling again failed to do so. **(b)(4)** followed-up with Sterling via voice message and email on December 19, 2024, and January 3, 2025. Sterling could not provide any evidence during the inspection that it cooperated with the manufacturer's investigation into this product. Sterling also could not provide any evidence that it coordinated with the manufacturer to identify illegitimate product in Sterling's possession or control, including product subsequently received. Evidence collected during the inspection indicates that Sterling continued to receive product with the same lot number as the product subject to the notification of illegitimate product, obtained through the same distributor, **(b)(4)**, until January 28, 2025. Your firm failed to quarantine such product and otherwise investigate. Your firm continued distributing product with the same lot number until February 3, 2025, nearly two months after you were first made aware of having distributed illegitimate product from this supplier labeled with this lot number.

Sterling did not notify FDA of the illegitimate product and was not able to demonstrate that it notified immediate trading partners that Sterling had reason to believe may have also received the illegitimate product. Invoices collected during the inspection indicate that Sterling knew or should have known that it distributed illegitimate product obtained from **(b)(4)** to other dispenser customers. Sterling nevertheless continued to receive product from **(b)(4)** containing the same lot number that was the subject of the notification of illegitimate product until January 28, 2024, and Sterling continued distributing product containing that lot number until February 3, 2025.

Sterling's actions are especially concerning because certain **(b)(4)** products, like those Sterling purchased from **(b)(4)**, **(b)(4)**[2] **(b)(4)**[3]. In addition, counterfeit **(b)(4)** has been the subject of multiple FDA[4] and **(b)(4)** consumer alerts[5, 6] over the past several years.

FDA has provided some specific transaction scenarios that could significantly increase the risk of suspect product entering the drug supply chain, and has recommended that trading partners be particularly diligent when engaging in such transactions.[7] Such scenarios include:

- Purchasing product that is generally in high demand in the U.S. market;
- Purchasing product that has been or is the subject of a public alert or announcement related to drug quality issued by a trading partner or FDA;
- Purchasing product that has been or is the subject of an FDA counterfeit alert;
- Purchasing product from a trading partner that has been involved in business transactions where they sold or delivered illegitimate product; and
- Purchasing product where the finished dosage form seems questionable (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).

Nevertheless, Sterling failed to comply with its verification obligations to ensure that the **(b)(4)** products purchased from **(b)(4)** were legitimate product. In addition, Sterling continued to distribute product it purchased from **(b)(4)** through February 5, 2025, well after your firm first became aware that **(b)(4)** may have distributed illegitimate product. And, as discussed above, in addition to failing to identify such product as suspect product, your firm was not able to demonstrate that Sterling conducted an investigation in coordination with trading partners after receiving a returned unit of counterfeit **(b)(4)** from a pharmacy to whom

your firm distributed product, responded to notifications of illegitimate product from trading partners, or made notifications of illegitimate product to trading partners.

5. Your firm failed to collect and maintain transaction information and transaction statements (FD&C Act Section 582(c)(1)).

Under section 582(c)(1) of the FD&C Act, wholesale drug distributors must not accept ownership of a product unless the previous owner provides the transaction information and transaction statement for the product, and must provide subsequent purchasers the transaction information and a transaction statement for the product. Under section 582(c)(1)(A)(v), a wholesale distributor must capture the transaction information and transaction statement for each transaction and maintain such information for not less than 6 years.

Sterling could not demonstrate that your firm collected and maintained transaction information and transaction statements that should have been received from **(b)(4)**. Sterling could not demonstrate that your firm shared transaction information and transaction statements with Sterling's downstream trading partners.

6. Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA. (FD&C Act Sections 582(c)(4)(A) and (B)).

Under sections 582(c)(4)(A) and (B) of the FD&C Act, wholesale drug distributors must have systems in place to enable the wholesale distributor to comply with the verification requirements of the DSCSA, including but not limited to:

- Identifying and determining whether a product in its possession or control is a suspect product;
- Promptly conducting an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which must include, among other things, investigating to determine whether the product is an illegitimate product and verifying the product at the package level;
- Quarantining and disposing of any illegitimate product in the wholesale distributor's possession or control;
- Taking reasonable and appropriate steps to assist a trading partner with disposition of an illegitimate product not in the possession or control of the wholesale distributor; and
- Maintaining records of the investigation of a suspect product and disposition of illegitimate product for not less than 6 years.

Your firm was not able to produce complete and accurate standard operating procedures (SOPs), or other systems related to compliance with the verification requirements of the DSCSA, that would enable Sterling to comply with the verification requirements under sections 582(c)(4)(A) and (B) of the FD&C Act. Sterling provided the FDA investigators with **(b)(4)** policy documents and standard operating procedures; none address the verification requirements of the DSCSA.

Your Response to the FDA Form 483

FDA has reviewed your March 26, 2025, response to our Form FDA 483 in detail. FDA acknowledges the corrective actions Sterling has taken and committed to, but FDA finds Sterling's response to be inadequate. Sterling's response does not provide adequate information about how Sterling will ensure compliance with the FD&C Act moving forward. In addition, Sterling's response does not acknowledge that, as early as November 2024, your firm knew or should have known that it was distributing prescription drugs without a wholesale distributor of prescription drugs license, and that by December 2024, your firm was distributing suspect and illegitimate product. Nevertheless, Sterling chose not to follow-up on those notifications.

In your firm's response, you state that you were not alerted to the fact the products at issue were potentially counterfeit, and therefore suspect and illegitimate.

During the course of their investigations, **(b)(4)** and the Arkansas and Mississippi BoP made multiple attempts to contact Sterling. **(b)(4)** tried to contact your firm on at least three (3) occasions regarding product it was investigating that had been distributed by your firm. You did not respond to assist in **(b)(4)** investigation. As a result of your lack of cooperation with **(b)(4)** investigation, **(b)(4)** was unable to provide you with additional information. Similarly, if Sterling had responded to the requests for information from the Mississippi and Arkansas State BoP, including the subpoena your firm received from Arkansas BoP, even to seek clarity about the requests, Sterling would have better understood the scope of the respective investigations. Instead, Sterling did not respond to the requests or the subpoena and did not participate in these investigations, in violation of the DSCSA requirements as outlined extensively above. The lack of specific language in these notifications and requests for information does not absolve Sterling of its obligations under the DSCSA. Sterling had significant notice and reason to know that **(b)(4)**, the manufacturer of the products distributed by Sterling, and multiple state BoP were investigating Sterling's distribution of prescription drug products, and your firm did not act.

Sterling's response does not explain how your firm will process notifications of illegitimate product and requests for information moving forward. It does not address how Sterling will ensure it is responsive and cooperative, as required by DSCSA, when contacted about suspect and illegitimate product investigations in the future.

Other reasons Sterling's response is insufficient include, but are not limited to, the following:

- Sterling's response explains that your firm is updating its policies and procedures for reviewing the credentials of vendors. Sterling has not yet explained what these policies and procedures will entail, nor provided a timeline for submitting these revised policies to FDA.
- In its response, Sterling explains that its vendor purchase order requires vendors to verify that all products sold to Sterling Distributors "have been stored following manufacturer recommendations and have never been previously distributed to any entity," and that products "are legitimate products purchased from FDA approved manufacturers." The response does not otherwise explain how Sterling plans to audit its vendors and ensure that product it receives is legitimate product from authorized sources.
- Given your firm's confusion over the prescription status of drugs you have previously distributed, Sterling's response does not explain how your firm will identify drugs as either an over-the-counter drug or a prescription drug.

DSCSA Resources

As explained above, your firm has failed to comply with a number of DSCSA provisions. Please see FDA's guidance documents,[8] including those listed below, for additional information about the DSCSA requirements noted above:

- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs, Final Guidance for Industry, December 2023, https://www.fda.gov/media/117950/download.
- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act, Final Guidance for Industry, March 2023, https://www.fda.gov/media/111468/download.
- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, Final Guidance, June 2021, https://www.fda.gov/media/88790/download.

Conclusion

Sterling's response to FDA Form 483 does not indicate that sufficient remediation efforts have been taken. FDA is sending this compliance letter to Sterling because of the inherent risk to the supply chain when firms do not comply with the provisions of the DSCSA.

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

Correct any violations promptly. Failure to promptly and adequately address the violations described herein may result in regulatory or legal action without further notice, including seizure and injunction.

Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations identified in this warning letter. Please include an explanation of each step being taken to prevent the recurrence of violations and include copies of related documentation. If you disagree with the characterization of the violations of the FD&C Act in this warning letter, include your reasoning and any supporting information for our consideration. If you cannot complete corrective actions within fifteen (15) working days, state the reason for the delay and the time within which you will complete the corrections.

Please send your electronic reply, or any questions regarding the contents of this letter, to: DSCSAInspections@fda.hhs.gov.

Please identify your responses with the unique identifier: CMS 706508.

Sincerely,
/S/

Sangeeta Vaswani Chatterjee, Pharm.D.
Acting Director
Office of Drug Security, Integrity, and Response

Office of Compliance
Center for Drug Evaluation and Research

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1 FDA maintains a reporting database that contains information submitted by wholesale drug distributors. Please note that reporting by a wholesale drug distributor provider does not mean the facility is licensed or approved by FDA or the facility is in compliance with applicable state and federal regulations. Check licensure of wholesale drug distributors and third-party logistics providers for more information.

2 **(b)(4)**

3 **(b)(4)**

4 **(b)(4)**

5 **(b)(4)**

6 **(b)(4)**

7 See FDA's *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*, Final Guidance, June 2021, https://www.fda.gov/media/88790/download.

8 FDA guidance documents can be found on our website: Drug Supply Chain Security Act Law and Policies | FDA