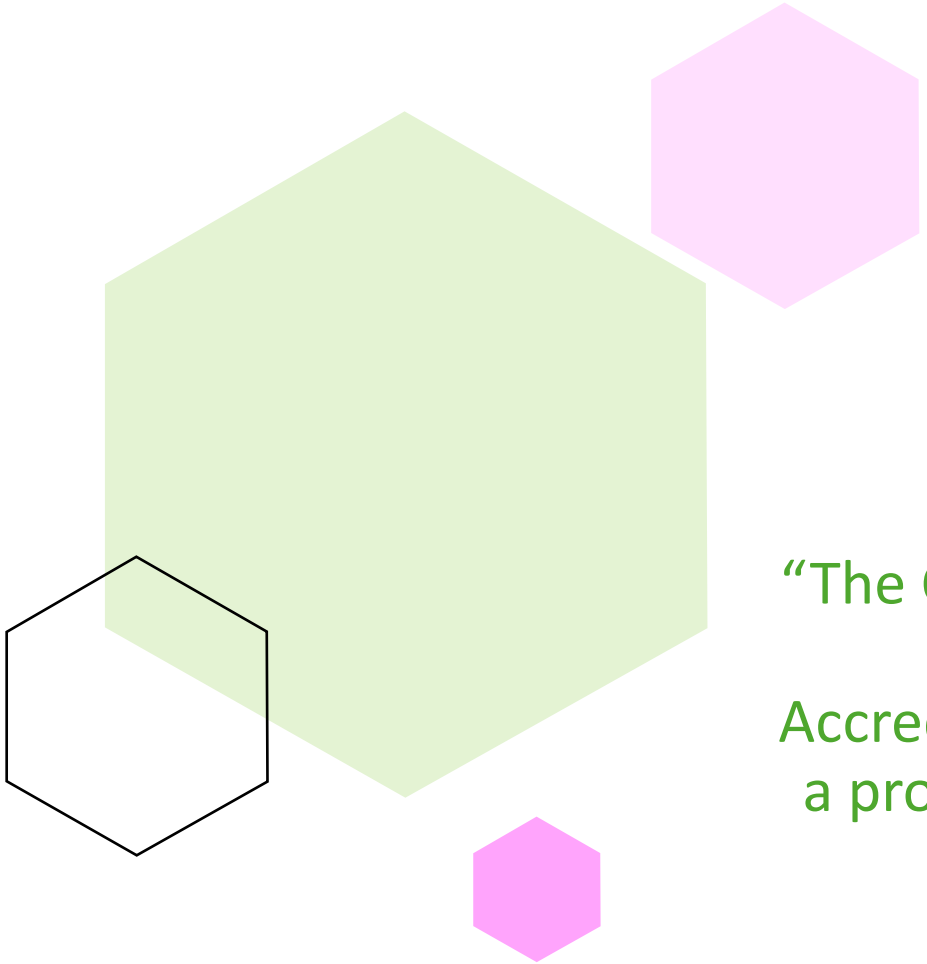
DRUG SUPPLY CHAIN SECURITY Act (DSCSA)

Requirements and Implementation Pearls

By

José Rodríguez-Pérez, PhD



“The Colegio de Farmacéuticos de Puerto Rico is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.”

Provider Number: 0151

Objectives

- Restate requirements within the Drug Supply Chain Security Act.
- Compare how the DSCSA impacts pharmacy profession in a variety of practice settings.
- Discuss best practices in implementing DSCSA in the industry manufacturing setting.
- Discuss best practices in implementing DSCSA in the wholesalers & distribution setting.
- Discuss best practices in implementing DSCSA in a health-system setting.
- Discuss reporting requirements set forth in the law in the different pharmacy practices settings
- Review current FDA enforcement

Agenda

- Introduction
- DSCSA Requirements and Responsibilities for Drug Manufacturers (Sponsor vs CMO)
- DSCSA Wholesale Distributor Requirements
- DSCSA Requirements for Pharmacist
- Drug Supply Chain Security Act Product Tracing Requirements | Frequently Asked Questions
- DSCSA Warning Letters

U.S. FOOD & DRUG ADMINISTRATION

PROTECT YOUR PATIENTS

Know your responsibilities under the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

The DSCSA was enacted in 2013 to further secure our nation's drug supply. It creates a tighter, closed prescription drug distribution system to **prevent** harmful drugs from entering the supply chain, **detect** harmful drugs if they do enter the supply chain, and enable rapid **response** when such drugs are found.

By law, pharmacies are required to:

Confirm the entities you do business with are licensed or registered

To help determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:

Check the registration of manufacturers and repackagers. See FDA's drug establishments current registration site database to confirm registration. You can find this database by searching for DECRS at www.fda.gov.

Check the licensing of wholesale distributors and third-party logistics providers. See FDA's wholesale drug distributor and third-party logistics providers reporting database. You can find this by searching for WDD/3PL database at www.fda.gov.

Check the licensing of pharmacies through the respective state authority.

Receive, store, and provide product tracing documentation

The law requires drugs to be traced as they move through the supply chain, and pharmacies must:

- Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it.
- Store the product tracing documentation you receive in paper or electronic format for six years.
- Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner. You do not need to provide this information when you dispense a prescription drug to a patient or if you sell to a pharmacy for dispensing to a specific patient.

Investigate and properly handle suspect and illegitimate drugs

Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:

- Quarantine and investigate suspect prescription drugs to determine if they are illegitimate; and
- If they are illegitimate, pharmacies should work with the manufacturer and take specific steps to ensure patients do not receive the illegitimate drugs. Pharmacies must also notify FDA and the trading partners they bought the drug from and sold the drug to. You can find more information by searching "drug notifications" at www.FDA.gov.

This information is only a summary of the DSCSA pharmacy requirements and is not a comprehensive list. Go to www.fda.gov to learn more about DSCSA, including the law and FDA's policies. You'll easily find information by searching "DSCSA."

Email us at drugtrackandtrace@fda.hhs.gov for more information.

www.fda.gov

1.1. What is the Drug Supply Chain Security Act (DSCSA)?

- The Drug Supply Chain Security Act (DSCSA) is a federal law enacted in 2013 to enhance the security and traceability of pharmaceutical products within the United States supply chain.
- The bill was signed by President Obama on 27th November, 2013 to amend the federal Food, Drug and Cosmetic Act to grant the FDA with more authority to regulate and monitor the manufacturing of compounded drugs.
- The DSCSA outlines steps to achieve an interoperable and electronic way to identify and trace certain prescription drugs at the package level as they move through the supply chain.
- This helps prevent harmful drugs from entering the U.S. drug supply chain, detect harmful drugs if they do enter the supply chain and enable rapid response to remove harmful drugs from the supply chain to protect patients.

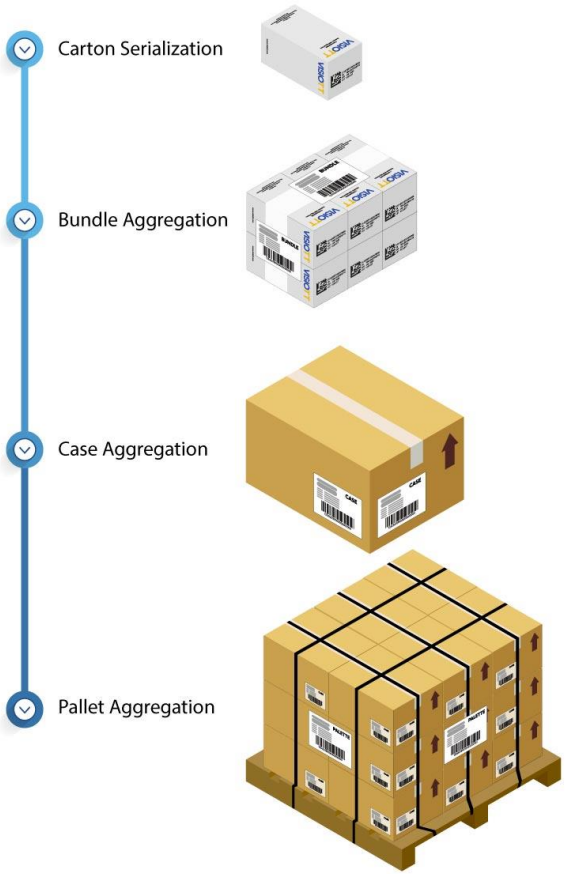
1.2. What is the Purpose of DSCSA?

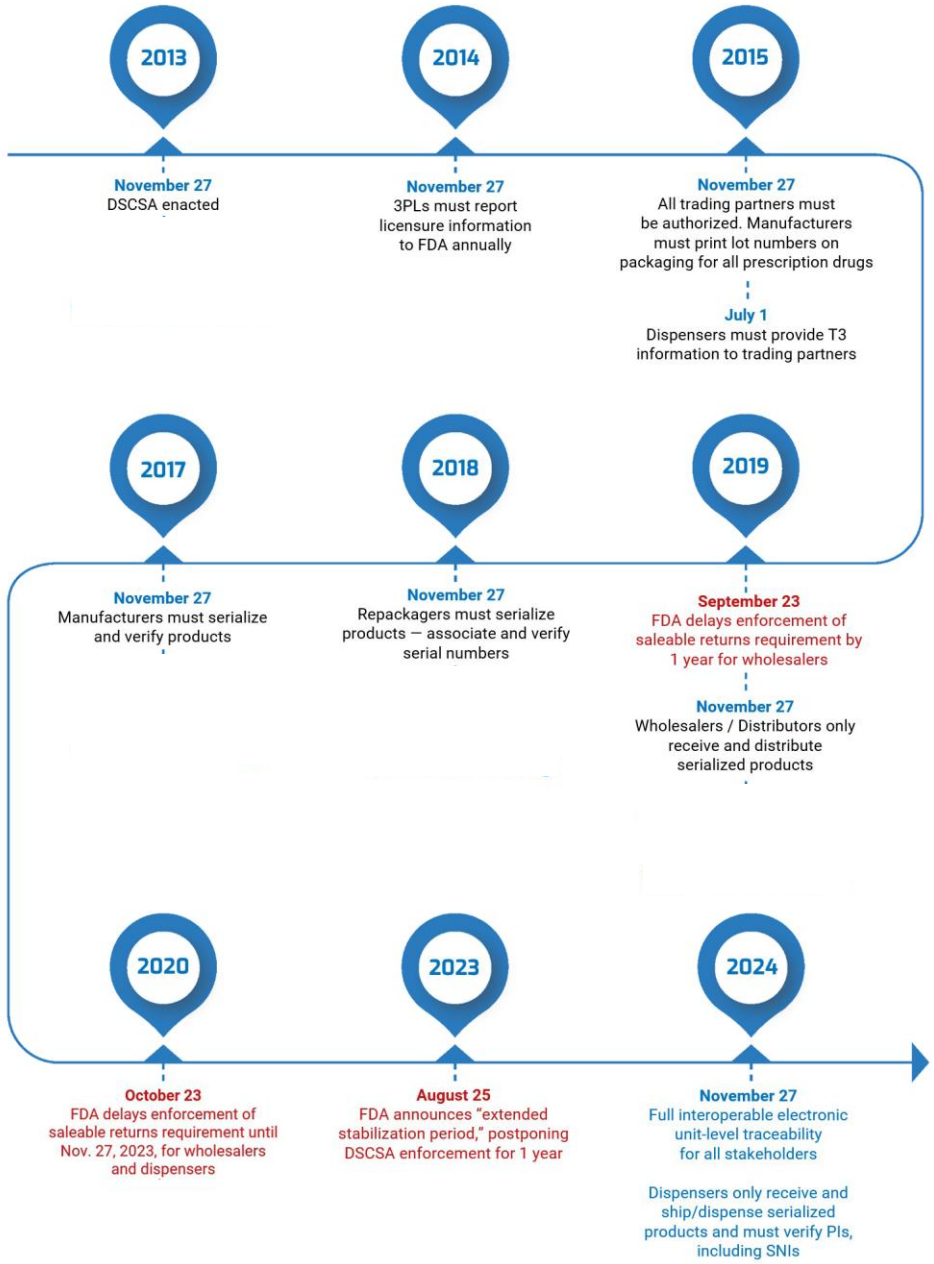
- The FDA's DSCSA and the EU's FMD share primary objectives revolving around enhancing patient safety and safeguarding the integrity of the pharmaceutical supply chain.
- DSCSA compliance and serialization play a vital role in ensuring the security and traceability of pharmaceutical products within the supply chain. By implementing serialization and adhering to the associated regulations, stakeholders can effectively track and trace drugs, verify authenticity, and effectively respond to any potential safety concerns.
- The DSCSA sets out a 10-year timeline to build an electronic, interoperable system for the exchange of transaction documentation [transaction information (TI), transaction history (TH) and transaction statements (TS)] to enable the tracing of prescription medicines, serialized at both the case and the smallest unit of sale, throughout the pharmaceutical supply chain.
- At the end of August, 2023, FDA announced a one-year stabilization period. This period extends enforcement flexibility until November 27, 2024 in order to give supply chain partners the time they need to stabilize data exchange, systems and processes developed to meet the final implementation requirements of DSCSA

1.3. The Significance of DSCSA and Serialization in the Pharmaceutical Supply Chain

- The DSCSA focus is to enhance the security and traceability of pharmaceutical products within the United States supply chain. Its primary objective is to safeguard patients from exposure to counterfeit, stolen, or otherwise harmful drugs.
- Manufacturers and repackagers must put a unique product identifier (PI), such as a bar code, on certain prescription drug packages. This must be able to be read electronically.

DSCSA





In June 2024, the FDA announced exemptions from certain requirements of section 582 Food, Drug and Cosmetic Act to small dispensers (pharmacies), and where applicable, their trading partners, until November 27, 2026.

1.4. Why Is DSCSA Compliance and Serialization Important?

- Serialization represents a crucial component of DSCSA compliance, encompassing the unique identification of individual drug packages or units through assigned serial numbers. Each serialized unit is linked with vital information, including the product's National Drug Code (NDC), lot number, expiration date, and other pertinent particulars. The utilization of unique serial numbers enables efficient tracking and tracing of each drug package's progress across various supply chain entities. Transaction data, history, and statements are exchanged, enabling the establishment of drug origins and facilitating prompt tracking in the event of recalls or safety concerns.

1.5. Who is Responsible for Compliance with DSCSA?

- Pharmaceutical distributors and dispensers bear the responsibility of authenticating received drug products by confirming the validity of serialized identifiers and scrutinizing the product's transaction history. This critical step ensures that the drugs being distributed are safer from counterfeiting or compromised in some way. In instances where suspected counterfeit or compromised drugs are identified, investigators can trace the drug's movement and identify potential points of supply chain integrity breaches.

Product tracing

- Manufacturers, wholesale distributors, repackagers, and many dispensers (primarily pharmacies) must provide certain information about the drug and who handled it each time it's sold:
    - Transaction information (TI) includes the product name; its strength and dosage form; its National Drug Code (NDC); container size and number of containers; lot number; transaction date; shipment date; and the name and address of the businesses from which and to which ownership is being transferred.
    - The transaction statement (TS) is a paper or electronic attestation by the business transferring ownership of the product that it has complied with the DSCSA.
    - A third type of information, Transaction history (TH), is an electronic statement with the TI for every transaction going back to the manufacturer. It is required before the November 27, 2023, deadline; it is not required after that date.

1.6. Is Compliance with DSCSA Required?

- The U.S. Food and Drug Administration (FDA) has provided manufacturers, distributors, and dispensers with a 10-year implementation period to fully comply with the federal regulations governing serialized unit traceability. The final deadline for complete compliance across the entire supply chain is November 27, 2023.

- The FDA recently announced a 1-year reprieve, to November 27, 2024, on enforcement activities for system-wide electronic interoperable systems for tracking products through the supply chain.

- The European Union's Falsified Medicines Directive (FMD), introduced in 2011 and finalized in 2019, serves as a regulatory framework sharing similar goals with the DSCSA. Its primary objective is to enhance the security of the pharmaceutical supply chain and prevent the introduction of falsified medicines. The FMD mandates the use of a unique identifier, akin to the serialization requirement in the DSCSA. Additionally, it requires distributors and dispensers to authenticate medicines by scanning the unique identifier in the European Medicines Verification System (EMVS).

1.7. What are the Consequences of DSCSA Non-Compliance?

- It is a criminal act if a company sells (intentionally or unintentional) non-serialized products. Failure to comply can lead to fines, suspension or revocation of license, and even potential imprisonment or civil penalties.

2.1. Responsibilities under the DSCSA in the US

Drug Sponsor/Manufacturer:	Contract Manufacturer:
• Product Serialization and Unique Identifier • Product Tracing and Verification • Transaction Information, History, and Statements (TIHRS) • Notification of Suspected Illegitimate Products • Notification of Discontinuance or Interruption of Distribution • Verification of Authorized Trading Partners	• Recordkeeping • Compliance with Sponsor Requirements • Transaction Information Exchange • Collaboration with Sponsors

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.1. Product Serialization and Unique Identifier

- Assigning a unique product identifier or serial number to each individual package of prescription drugs they manufacture. The identifier must include:
    - the National Drug Code (NDC),
    - a serial number,
    - a lot number, and
    - an expiration date.

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.2. Product Tracing and Verification

- Establishing systems for tracing and verifying the authenticity of their products as they move through the supply chain with implementation of mechanisms to track each drug package from manufacture to dispensing.

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.3. Transaction Information, History, and Statements (TIHRS)

- Ensuring transparency and security when transferring ownership of products to authorized trading partners, by providing:
    - transaction information,
    - transaction history, and
    - transaction statements.

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.4. Notification of Suspected Illegitimate Products

- Quarantining and investigating promptly if becoming aware of a suspect or illegitimate product within their supply chain. If the product is confirmed to be illegitimate, they must notify:
    - the FDA,
    - trading partners, and
    - other relevant parties.

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.5. Notification of Discontinuance or Interruption of Distribution

- Providing advance notification to relevant stakeholders and the FDA if they experience an interruption in supply or plan to discontinue the distribution of a product.

2.2. DSCSA Requirements for Drug Sponsors (Manufacturers)

2.2.6. Verification of Authorized Trading Partners

- Verifying the authorization of trading partners to ensure their legitimacy before engaging in transactions with other entities in the supply chain.

2.3. DSCSA Requirements for Contract Manufacturers

- Recordkeeping
- Compliance with Sponsor Requirements
- Transaction Information Exchange
- Collaboration with Sponsors

3. DSCSA Wholesale Distributor Requirements

- Annual Licensure Reporting Requirements
- FDA's Reporting Database
- Information that Must be Reported to FDA
- Annual Reporting using CDER Direct

3.1. Annual Licensure Reporting Requirements

- Wholesale drug distributors and third-party logistics providers must be appropriately licensed and report licensure and other information to FDA annually to be authorized trading partners under the Drug Supply Chain Security Act.

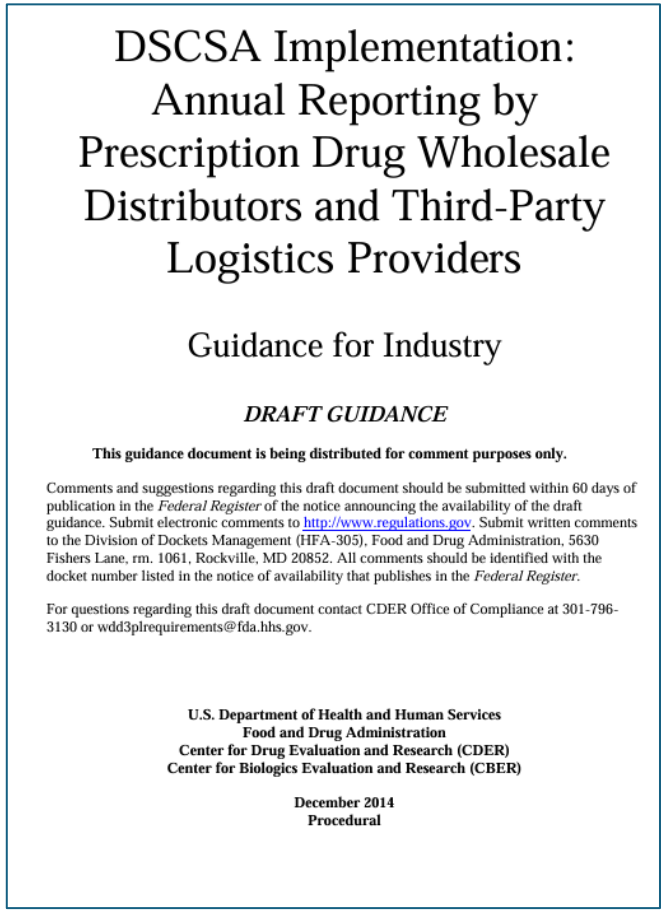
3.2. FDA's Reporting Database

- The reporting database contains information submitted by wholesale drug distributors and third-party logistics providers. Each line of the database represents a license for a particular facility. One facility may have multiple licenses and therefore multiple lines may be listed in the database. This database is updated every business day.

- Reporting by a wholesale drug distributor or third-party logistics provider does not mean the facility is licensed or approved by FDA or the facility is in compliance with applicable state and federal regulations.

3.3. Information that Must be reported to FDA

- Wholesale drug distributors and third-party logistics providers must report certain information to FDA, including:
  - state licensure and contact information for facilities
  - significant state or federal disciplinary actions



DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

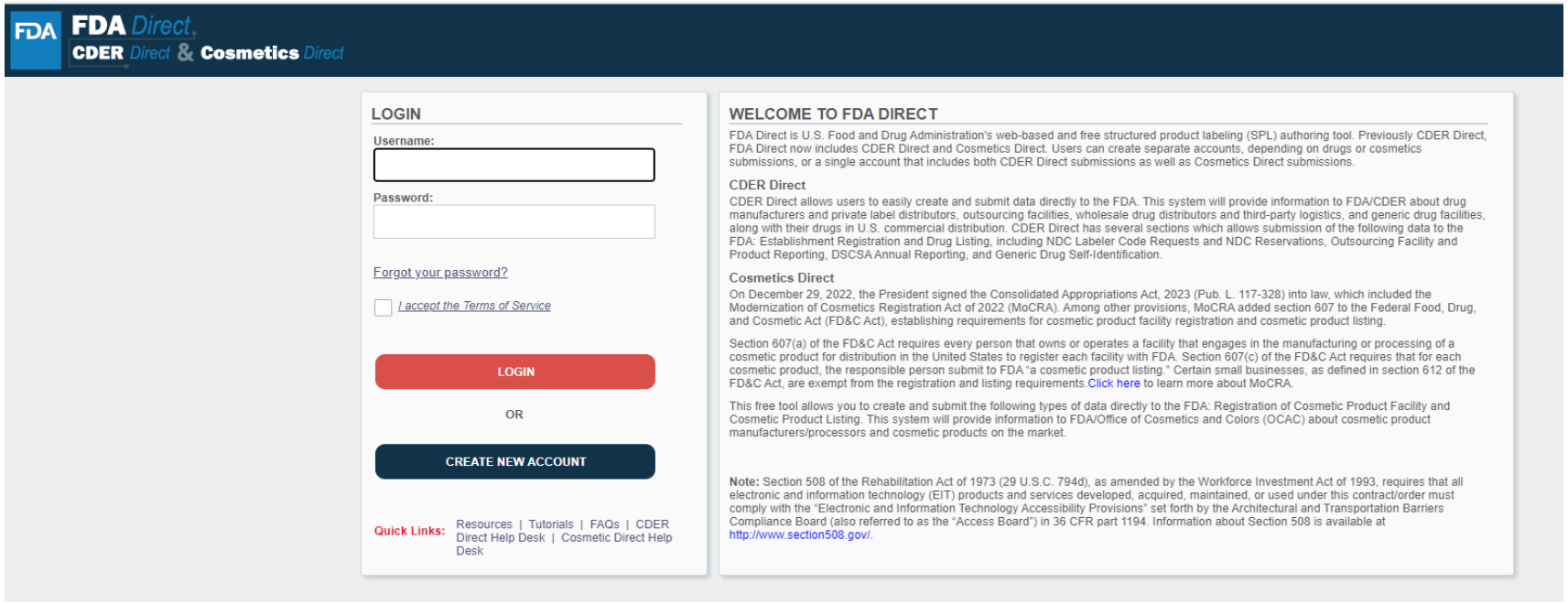
For questions regarding this draft document contact CDER Office of Compliance at 301-796-3130 or wdd3plrequirements@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014
Procedural

3.4. Annual Reporting using CDER Direct

- Annual reporting submissions by wholesale drug distributors and third-party logistics providers can be made using CDER Direct.
- Updates to an annual report can be done through CDER Direct by updating a previous submission. An entity also can withdraw its report through CDER Direct if the entity determines that it has reported in error.



4. DSCSA Requirements for Pharmacists

Utilize DSCSA Requirements to Protect Your Patient

4.1. Definition of dispenser

- Pharmacists, or “dispensers” as referred to under the Drug Supply Chain Security Act, have responsibilities to protect patients from receiving harmful drug products.

- DSCSA includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

- DSCSA creates a tighter, closed prescription drug supply chain to:

  - prevent harmful drugs from entering the supply chain
  - detect harmful drugs if they do enter the supply chain
  - respond rapidly and effectively when harmful drugs are found

4.1. Definition of dispenser cont.

DSCSA defines a dispenser as:

- A retail pharmacy;
- A hospital pharmacy;
- A group of chain pharmacies under common ownership and control that do not act as a wholesale distributor; or
- Any other person authorized by law to dispense or administer prescription drugs and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor

4.2. Role of small dispensers

- The Drug Supply Chain Security Act (DSCSA) recognizes the role of small dispensers (pharmacies) in the drug supply chain.
- FDA provides ways to assist small dispensers that provide drugs to patients with a prescription meet the requirements of the law.

4.3. Small dispenser assessment

- DSCSA directs FDA to contract with a private, independent consulting company to conduct a technology and software assessment that looks at the feasibility of small dispensers conducting interoperable, electronic tracing of products at the package level. The assessment must determine whether for such dispensers:
  - the necessary software and hardware are readily accessible
  - the necessary software and hardware are prohibitively expensive to obtain, install and maintain
  - the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors
- The law also instructs FDA to consider the assessment and provide provisions for alternative methods of compliance, including:
  - establishing a process for small dispensers to request a waiver, and
  - establishing timelines for compliance if it is determined the enhanced drug distribution security requirements would result in undue economic hardship.

4.4. Confirm the entities you do business with are licensed and registered

- To help determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers and pharmacies) are licensed or registered:
    - Check the registration of manufacturers and repackagers
    - Check the licensing of wholesale distributors and third-party logistics providers
    - Check the licensing of pharmacies through the respective state authority

4.5. Receive, store and provide product tracing documentation

- The law requires drugs to be traced as they move through the supply chain, and pharmacies must:

  - Only accept prescription drugs that are accompanied by product tracing documentation. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it.
  - Store the product tracing documentation you receive for six years.
  - Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner. You do not need to provide this information when you dispense a prescription drug to a patient or if you sell to a pharmacy for dispensing to a specific patient.

4.6. Investigate and properly handle suspect and illegitimate drug

- Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated or unfit for distribution, including steps to:
  - Quarantine and investigate suspect prescription drugs to determine if they are illegitimate; and
  - If they are illegitimate, pharmacies should work with the manufacturer and take specific steps to ensure patients do not receive the illegitimate drugs. Pharmacies must also notify FDA and the trading partners they bought the drug from and sold the drug to.

Notify FDA within 24 hours

- The DSCSA requires certain trading partners — manufacturers, repackagers, wholesale distributors and dispensers — to notify FDA and all appropriate immediate trading partners within 24 hours after determining a product is illegitimate.
- Manufacturers also are required to notify FDA and appropriate trading partners within 24 hours after determining a product is at high risk for illegitimacy.
- Submit illegitimate product notifications through the 3911 platform in CDER NextGen, which is the agency's preferred method, or complete Form FDA 3911 and submit via email. Trading partners should provide information:
    - about the person or entity initiating the notification,
    - the product that has been determined to be illegitimate and subject of the notification and
    - a description of the circumstances surrounding the event that prompted the notification.

Illegitimate Products

- An illegitimate product is a product for which credible evidence shows the product:
  - is counterfeit, diverted or stolen;
  - is intentionally adulterated and would result in serious adverse health consequences or death;
  - is the subject of a fraudulent transaction; or
  - appears otherwise unfit for distribution and would be reasonably likely to result in serious adverse health consequences or death.

4.7. Small dispenser exemption

- FDA is issuing exemptions from certain requirements of section 582 of the FD&C Act to small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the DSCSA.

- A dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians. Pharmacies must make their own determination of whether they meet the definition of a small dispenser.

- FDA urges small dispensers to continue their efforts to implement the necessary measures to comply with the enhanced drug distribution security requirements. Small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA or inform the agency.

Requesting a Waiver or Exemption Beyond the Stabilization Period

- FDA previously provided a one-year stabilization period, for enhanced drug distribution security requirements of section 582 of the FD&C Act for all trading partners which ends on November 27, 2024. The agency is not extending the stabilization period beyond November 27, 2024.
-
- Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, may request a waiver or exemption from those requirements.

5.1. Is the pedigree provision of the Prescription Drug Marketing Act (PDMA) still in effect?

- No. As of January 1, 2015, the “pedigree” provision of the Federal Food, Drug and Cosmetic (FD&C) Act (added by the PDMA of 1987) that required certain wholesale distributors to provide to the person who received the drug “…a statement…identifying each prior sale, purchase or trade of such drug…” no longer exists and is no longer in effect.

- DSCSA removed the drug pedigree language and replaced it with new language in section 503(e) of the FD&C Act, which pertains to new licensing requirements and uniform national standards for wholesale distribution of prescription drugs.

- DSCSA also added product tracing requirements in section 582 of the FD&C Act to provide and capture product tracing information associated with each transaction for most human prescription drugs in finished form.

5.2. Which drugs do and do not fall under the DSCSA requirements for product tracing, product identifier, authorized trading partner and verification?

Section 582 of the FD&C Act defines a product as “a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets and lyophilized products before reconstitution).”

DSCSA requirements do not apply to:

- Over-the-counter drugs
- Animal drugs
- Blood or blood components intended for transfusion
- Radioactive drugs or biologic products
- Imaging drugs
- Certain intravenous (IV) drugs
- Medical gases
- Certain homeopathic drugs
- Lawfully compounded drugs

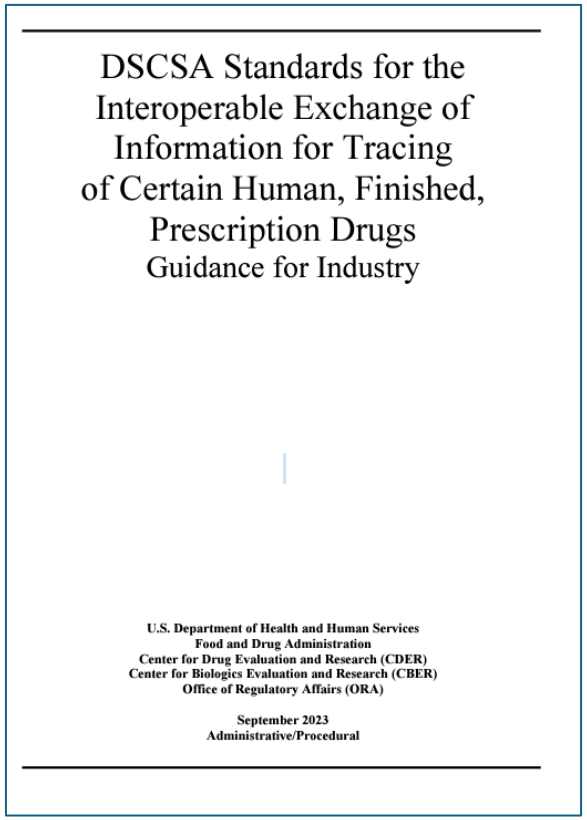
5.3. Who needs to comply with DSCSA requirements for product tracing, product identifier, authorized trading partner and verification?

- Product tracing, product identifier, authorized trading partner and verification requirements in section 582 of the FD&C Act apply to trading partners as defined in section 581(23)(A) of the FD&C Act which includes drug manufacturers, repackagers, wholesale distributors and dispensers (primarily pharmacies) need to comply with these requirements need to comply with these requirements.

- An entity that meets more than one trading partner definition must comply with all applicable requirements in section 582 of the FD&C Act, but not duplicative requirements. Visit section 582(a)(1) of the FD&C Act for more information.

5.4. Does FDA have standardized forms for transaction information, transaction history and transaction statements that I can use?

- No.
- FDA has not established standardized forms for such product tracing information. The agency issued a final guidance, **"DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information,"** that identifies standards to help trading partners understand the methods available for exchanging product tracing information.


DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

September 2023
Administrative/Procedural

5.5. When a pharmacy sells a product to another pharmacy, do the DSCSA product tracing requirements related to transaction history, transaction information and transaction statements apply?

- Yes, except for sales by a dispenser to another dispenser to fulfill a specific patient need.
- The law defines a “specific patient need” as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient and does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. Visit sections 581(19) and 582(d)(1)(A)(ii) of the FD&C Act for more information.

5.6. Do veterinarians or veterinary clinics have any obligations under product tracing or other obligations under DSCSA when they use human prescription drugs in animals?

- No.
- If a veterinarian or a veterinary clinic uses human prescription drugs only in animals in accordance with section 512(a)(5) of the FD&C Act, the veterinarian or veterinary clinic is excluded from the definition of dispenser under section 581(3)(B) of the FD&C Act.

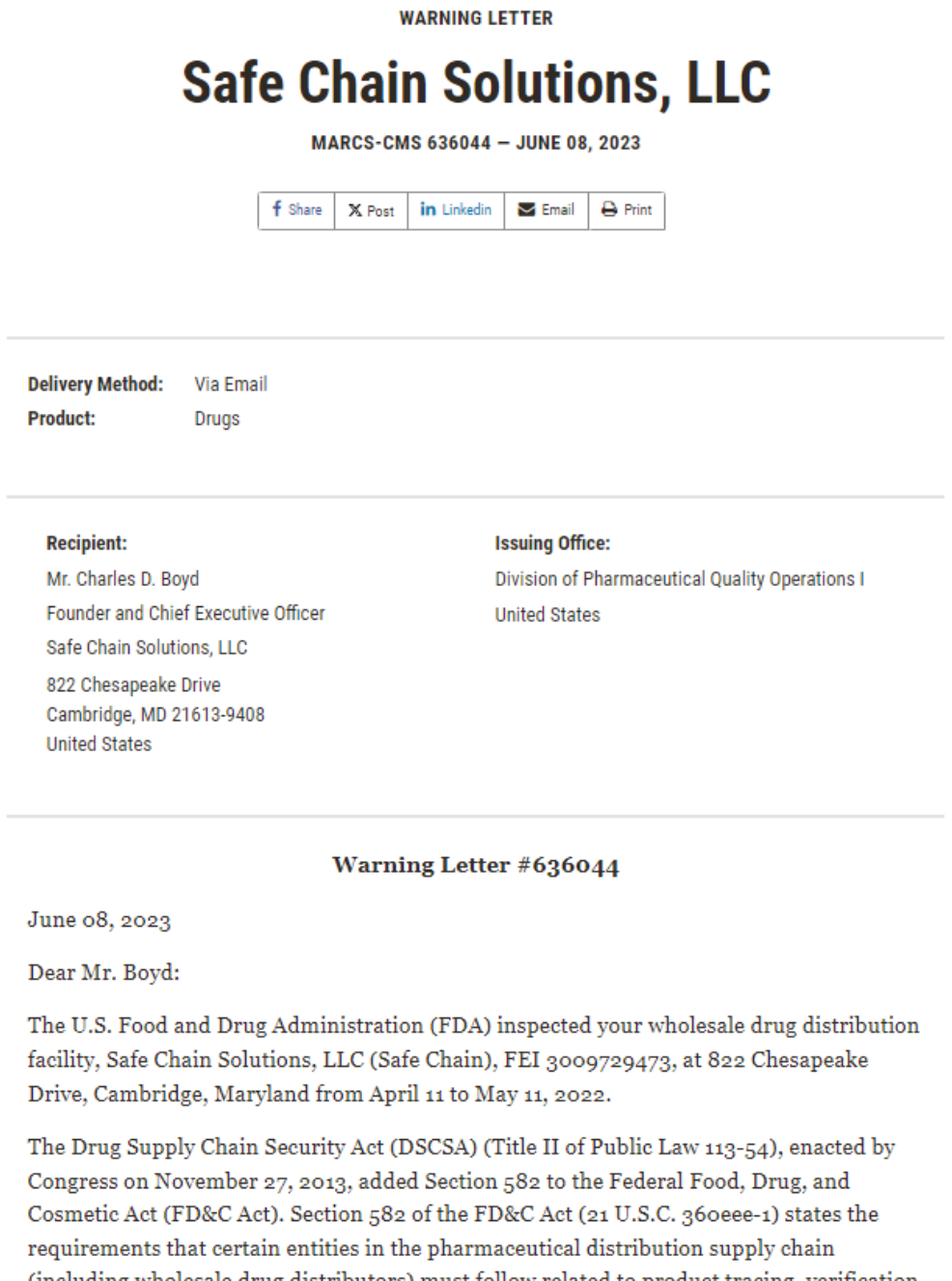
5.7. I am being asked to obtain a Global Location Number (GLN) by my suppliers (e.g., wholesale distributor or manufacturer). Is this a requirement under DSCSA?

- No.
- DSCSA does not require trading partners to obtain a specific location identifier, such as a GLN. However, for the enhanced drug distribution security requirements in section 582(g)(1) of the FD&C Act, FDA recommends using the GS1 Electronic Product Code Information Services (EPCIS) standard to enable secure, interoperable, electronic data exchange among the pharmaceutical distribution chain. Your trading partner may ask you to obtain a GLN, which is a data element of EPCIS, as a business requirement to facilitate data exchange using EPCIS.

- Visit section VIII of our final guidance, “DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information.”

6. DCSA Warning Letters

- This warning letter, dated June 8, 2023, was issued to Safe Chain Solutions, LLC and addresses DSCSA violations related to the wholesale distributor's repeated instances of distributing costly counterfeit HIV antiviral drugs that Safe Chain had sourced from unauthorized trading partners, even after having received reports from downstream trading partners that suggested the drugs were counterfeit.



WARNING LETTER

Safe Chain Solutions, LLC

MARCS-CMS 636044 — JUNE 08, 2023

Share | Post | Linkedin | Email | Print

Delivery Method: Via Email
Product: Drugs

Recipient:
Mr. Charles D. Boyd
Founder and Chief Executive Officer
Safe Chain Solutions, LLC
822 Chesapeake Drive
Cambridge, MD 21613-9408
United States

Issuing Office:
Division of Pharmaceutical Quality Operations I
United States

Warning Letter #636044

June 08, 2023

Dear Mr. Boyd:

The U.S. Food and Drug Administration (FDA) inspected your wholesale drug distribution facility, Safe Chain Solutions, LLC (Safe Chain), FEI 3009729473, at 822 Chesapeake Drive, Cambridge, Maryland from April 11 to May 11, 2022.

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) states the requirements that certain entities in the pharmaceutical distribution supply chain (including wholesale drug distributors) must follow related to product tracing, verification, and authorized trading partners. This warning letter summarizes significant violations of

Safe Chain Solutions, LLC DSCSA Violations

During FDA's inspection, our investigators observed that your firm failed to comply with various requirements of the DSCSA:

- **1. Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA (FD&C Act Section 582(c)(4)(A) & (B)).**
  - Your firm was not able to demonstrate systems that would enable Safe Chain to comply with a number of verification requirements required by the DSCSA. For example, your document, "SOP for Suspect & Illegitimate Product" lacked sufficient detail or instruction to enable Safe Chain to adequately:
  - ✓ Identify suspect product
  - ✓ Conduct an investigation (including validating any applicable transaction history and transaction information) to determine whether a suspect product is an illegitimate product in coordination with trading partners
  - ✓ Handle an illegitimate product notification
  - ✓ Handle a request for verification of a suspect product from FDA
  - ✓ Make notifications of cleared product, and
  - ✓ Maintain adequate records relating to the investigation of suspect product or the disposition of illegitimate product.

Safe Chain Solutions, LLC DSCSA Violations

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

- The DSCSA requires that trading partners of wholesale distributors meet the applicable requirements for being authorized trading partners.
- Between July, 2020 and March, 2021, your firm purchased drug products from wholesale drug distributors that were not authorized trading partners according to sections 581(2) and 503(e) of the FD&C Act. For example, your firm purchased prescription drug products from wholesale distributors Gentek and Boulevard 9229 LLC.
- However, FDA has no record of Gentek or Boulevard 9229 LLC ever submitting the required annual reports to FDA regarding state licensure as required by section 503(e) of the FD&C Act. In addition, Boulevard 9229 LLC provided your firm with a fraudulent license. Therefore, Boulevard 9229 LLC not only failed to report to FDA, but it was also never appropriately licensed as required by section 503(e)(1)(A) and 582(a)(6) of the FD&C Act.

Safe Chain Solutions, LLC DSCSA Violations

- **3. Your firm failed to maintain records of suspect product investigations (FD&C Act Section 582(c)(4)(A)(iii)).**

- The DSCSA requires that wholesale distributors maintain records of investigations of suspect product for not less than 6 years. (FD&C Act section 582(c)(4)(A)(iii)). Your firm was both unable to provide any written documentation of what products were held in or released from quarantine, and unable to provide records explaining how suspect product was quarantined.
- In addition, while you were able to produce some correspondence pertaining to the various lots of suspect product, you were unable to provide records about when and how investigations took place to determine whether suspect product was illegitimate.

Safe Chain Solutions, LLC DSCSA Violations

- **4. Your firm failed to respond to a notification of illegitimate product (FD&C Act Section 582(c)(4)(B)(iii)).**

- Upon receiving a notification of illegitimate product, a wholesale distributor must identify all illegitimate product subject to such notification in its possession or control, including any product that is subsequently received. (FD&C Act section 582(c)(4)(B)(iii)).
- You are also required to quarantine such product within your possession or control from product intended for distribution (FD&C Act sections 582(c)(4)(A)(i)(I) and 582(c)(4)(B)(i)(I)) and investigate the product as suspect product (FD&C Act sections 582(c)(4)(A)(i)(II) and 582(c)(4)(B)(iii)).
- You were not able to provide evidence that you appropriately responded to notifications of illegitimate product.

Summary

This presentation covered the basic elements of the Drug Supply Chain Security Act (DSCSA), a federal law enacted in 2013 to enhance the security and traceability of pharmaceutical products within the United States supply chain.

Specifically, it focused on:

- ✓DSCSA Requirements and Responsibilities for Drug Manufacturers (Sponsor vs CMO)
- ✓DSCSA Wholesale Distributor Requirements
- ✓DSCSA Requirements for Pharmacist
- ✓Drug Supply Chain Security Act Product Tracing Requirements | Frequently Asked Questions
- ✓DSCSA Warning Letters

Pre-Test

1. The DSCSA includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs. True False
2. DSCA creates a tighter, closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect counterfeit drugs if they do enter the supply chain, and enable rapid response when such drugs are found. True False
3. The pharmacy needs to determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered. True False
4. The law requires drugs to be traced as they move through the supply chain, and pharmacies must: Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it. True False
5. Store the product tracing documentation you receive in paper or electronic format for ten years. True False
6. FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners not later than 24 hours after making the determination. True False

Post-Test

1. The DSCSA includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs. True False
2. DSCA creates a tighter, closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect counterfeit drugs if they do enter the supply chain, and enable rapid response when such drugs are found. True False
3. The pharmacy needs to determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered. True False
4. The law requires drugs to be traced as they move through the supply chain, and pharmacies must: Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. If the trading partner you purchased the drugs from does not provide all this documentation, work with them to promptly get it. True False
5. Store the product tracing documentation you receive in paper or electronic format for ten years. True False
6. FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners not later than 24 hours after making the determination. True False

REFERENCES

- https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
- https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies
- https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/safe-chain-solutions-llc-636044-06082023
- https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients

Para obtener el certificado de Educación Continua

1. Log in en tu cuenta de **CFPR.org**
2. Click en **MI CUENTA**
3. Click en **HISTORIAL DE CURSOS**
4. Seleccionar el curso
5. Completar la evaluación y Prueba
6. Guardar o imprimir el Certificado

ACCESS CODE

CPE MONITOR

CODE

Tiena hasta el 5 de Octubre para completer la evaluación y prueba y poder obtener su certificado

Thank you

- José Rodríguez Pérez PhD
- Email: pepe@calidapr.com
- Phone: 787.705.7272