



# Regulatory Education for Industry (REdI): **GENERIC DRUGS FORUM**

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## **The Drug Supply Chain Security Act: Readiness and Implementation**

**Connie Jung, RPh, PhD**

U.S. Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Compliance  
Office of Drug Security, Integrity, & Response



# Overview of Presentation

- **Review the new requirements of the Drug Supply Chain Security Act (DSCSA)**
- **Review Implementation Updates**



# Are you ready for the Drug Supply Chain Security Act? (1)

[Updated 12/23/2014] FDA [issued guidance](#) to inform industry that we do not intend to take action against manufacturers, wholesale distributors, or repackagers who do not, prior to May 1, 2015, provide or capture the product tracing information required by sections 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This action is to minimize possible disruptions in the distribution of prescription drugs in the United States.

## ✓ Become familiar with the law

There are new requirements under the [Drug Supply Chain Security Act \(DSCSA\)](#) for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners). Some requirements began in November 2014 and several key requirements begin at various stages in 2015. The new requirements, development of standards, and the system for product tracing will continue to be phased in over the next nine years. FDA will continue working with trading partners and other stakeholders to effectively implement the new requirements.

## ✓ Work with your trading partners to ensure they are familiar with the law

It is important that all trading partners understand their responsibilities and work together to help facilitate efficient distribution and availability of drug products in the United States.

## ✓ Report licensure (third-party logistics providers and wholesale distributors)

Start Date	Trading Partner(s)	Requirement
11/27/2014	Third-party logistics providers	Report licensure and other information to FDA
1/1/2015	Wholesale distributors	Report licensure and other information to FDA

To assist third-party logistics providers and wholesale distributors to comply with the new reporting requirements, FDA published a draft guidance, [Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers](#) (December 2014). The draft guidance outlines the information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting using FDA's [CDER Direct Electronic Submissions Portal](#). FDA posted a [webinar](#) that provides an overview of annual reporting requirements.



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# Become familiar with the law (1)





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## Title II: DSCSA

- New definitions (Section 581)
- New requirements for product tracing, verification, notification, record keeping, and product identification (Section 582)

Link to Public Law 113-54:

<http://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf#page=13>





# Become familiar with the law (2)

## Overview – Major provisions

- **Product tracing (by 2015 lot-level, by 2023 package-level)**
- **Product verification**
  - Quarantine and investigation (steps for detection and response)
  - Notification, Recordkeeping
- **Product identification (applied to product beginning 2017)**
- **Wholesale distributor and Third-party logistics provider standards for licensure**
- **Enhanced system (electronic, interoperable system to trace products at the package-level by 2023)**
- **Penalties**
- **National uniform policy**



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# **Work with trading partners to ensure they are familiar with the law**

- **Trading partners should:**
  - understand their responsibilities
  - work together to help facilitate efficient distribution and availability of prescription drugs
- **Communicate with your trading partners**
- **Utilize FDA communications and resources**



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# Report Licensure (Third-party logistics providers and Wholesale distributors)

- **Reporting licensure to FDA**

- 3PL : starting 11/27/2014
- Wholesale distributors: starting 1/1/2015

- **Annual Reporting Webpage:**

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm>

- FDA's CDER Direct Electronic Submission Portal
- Guidance explains who, what, when, and how



# Are you ready for the Drug Supply Chain Security Act? (2)

## ✓ Provide product tracing information (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"><li>• Manufacturers</li><li>• Repackagers</li><li>• Wholesale distributors</li></ul>	Lot-level product tracing: provide transaction information, history, and statement
7/1/2015	Dispensers (primarily pharmacies)	Lot-level product tracing: provide transaction information, history, and statement

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new product tracing requirements, FDA has published a draft guidance for industry, [DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information](#) (November 2014).

- Accept ownership of product with applicable transaction information, transaction history, and transaction statements.
  - If your trading partner does not provide the proper transaction documentation, work with your trading partner to promptly get the proper documentation and to minimize disruption in the supply chain.



# Provide product tracing information (1)

## Product Tracing

- Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and dispensers (beginning 7/1/2015) in the drug supply chain must provide information about a drug and who handled it each time it is sold in the U.S. market.\*
- This transaction documentation consists of:
  - Transaction *information (TI)* (which include lot number of product (except for certain wholesale drug distributor transactions))
  - Transaction *history (TH)*
  - Transaction *statement (TS)*

\* See DSCSA Implementation: Product Tracing Requirements — Compliance Policy Guidance for Industry, Issued 12/23/2014





# Provide product tracing information (2)

## Definitions

### **Transaction Information (TI):**

- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.

**Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.**

### **Transaction Statement (TS): A statement, in paper or electronic form, that the entity transferring ownership in a transaction—**

- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.



# Provide product tracing information (3)

## **Draft Guidance: DSCSA Standards for the Interoperable Exchange of Information...How to Exchange Product Tracing information**

- **Can use or build on current systems and processes to comply with the product tracing requirements**
- **Can use current paper-based or electronic-based methods as long as the selected method(s) allow product tracing information to be exchanged in a manner that complies with the applicable requirements.**
- **Examples of methods that could be used include, but are not limited to:**
  - paper or electronic versions of invoices;
  - paper versions of packing slips;
  - Electronic Data Interchange (EDI) standards, such as the Advance Ship Notice (ASN),
  - EPCIS (Electronic Product Code Information Services)
- **Email or web-based platforms are acceptable for transmitting or providing access to the product tracing information, as long as the information that is captured, maintained, and provided is in compliance with the law.**
- **Public docket comments are being reviewed**



# Provide product tracing information (4)

## Manufacturer Specific

### Manufacturers -

- Shall provide to subsequent owner TI, TH, and TS, prior to, or at the time of each transaction (transfer of product with change of ownership) of a product, in a single document (paper or electronic).
- Beginning 11/27/17, shall provide TI, TH, TS in electronic format.

Exception: may continue to use paper format to licensed health care practitioners authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course or professional practice.



# Are you ready for the Drug Supply Chain Security Act? (3)

## ✓ Know how to handle suspect and illegitimate product (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"><li>• Manufacturers</li><li>• Repackagers</li><li>• Wholesale distributors</li><li>• Dispensers (primarily pharmacies)</li></ul>	Establish systems for verification and handling of suspect or illegitimate product.

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new verification requirements, FDA published the draft guidance for industry, [Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification](#) (June 2014). FDA posted a [webinar](#) that reviews how to identify suspect product and the process for notification.

- Establish systems to:
  - Quarantine and investigate *suspect product* to determine if it is illegitimate.
  - Notify FDA and immediate trading partners, if *illegitimate product* is found.



# Know how to handle suspect and illegitimate product (1)

## Verification

- **No later than 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements**
  - Must be able to respond to verification requests from Secretary about suspect product
  - Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  - Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  - Respond to notifications of illegitimate product
  - Recordkeeping
- **Verification requirements change once product is serialized.**  
(starting in 2017 for manufacturers, 2018 for repackagers, 2019 for wholesale distributors and 2020 for dispensers)





# Know how to handle suspect and illegitimate product (2)

## Draft Guidance: Identification of Suspect Product and Notification

- Describes scenarios that increase risk of suspect product for entering supply chain
- Recommendations on how to identify and make determination of suspect product
- Sets forth process to notify FDA and consult with FDA to termination notifications about illegitimate product

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf>

- Comment period ended August 11, 2014
- Proposes draft form FDA 3911: Drug Notification
- Comments are under review



# Know how to handle suspect and illegitimate product (3)

## Request for Information

When responding to **requests for information** from FDA or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect or illegitimate product,

- **Manufacturers, Wholesale Distributors, Repackagers:**

Shall provide applicable TI, TH, and TS, not later than 1 business day, not to exceed 48 hours after receiving request

- **Dispensers:**

Shall provide applicable TI, TH, TS not later than 2 business days (or another reasonable time as determined by FDA) after receiving request; shall not include lot, initial transaction date or initial shipment date unless such information was provided; may respond in paper or electronic format; certain limitations to information requests apply until November 27, 2017.



# Are you ready for the Drug Supply Chain Security Act? (4)

## ✓ Confirm authorized trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	<ul style="list-style-type: none"><li>• Manufacturers</li><li>• Repackagers</li><li>• Wholesale distributors</li><li>• Dispensers</li><li>• Third-party logistic providers</li></ul>	Must be authorized, as defined by the FD&C Act

- Check with your trading partner directly to confirm they are authorized, or
  - For manufacturers and repackagers, check [FDA's drug establishment registration database](#) for registration;
  - For wholesale distributors, third-party logistic providers and dispensers, you can check with your respective state authority to confirm licensure.

Note, third-party logistic providers are considered to be licensed under the DSCSA until the effective date of the third-party logistic provider licensing regulations issued by FDA, unless the third-party logistic provider is licensed by a state having a specific third-party logistic provider licensing program.

For more information about DSCSA implementation and new requirements to enhance drug distribution security, please visit [FDA's Drug Supply Chain Security Act web page](#).



# Confirm authorized trading partners (1)

## Authorized Trading Partners

- **Manufacturers and Repackagers:** valid registration with FDA
- **Wholesale distributors:** valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective if possesses “valid license under State law”
- **Third-party logistic provider:** valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective, unless FDA makes certain findings and gives notice
- **Dispensers:** valid State license

**Beginning 1/1/2015 - trading partners must be “authorized”**



## **Confirm authorized trading partners (2)**

- **Check with your trading partner directly**
- **FDA resources for registration**
- **State resources for licensure**



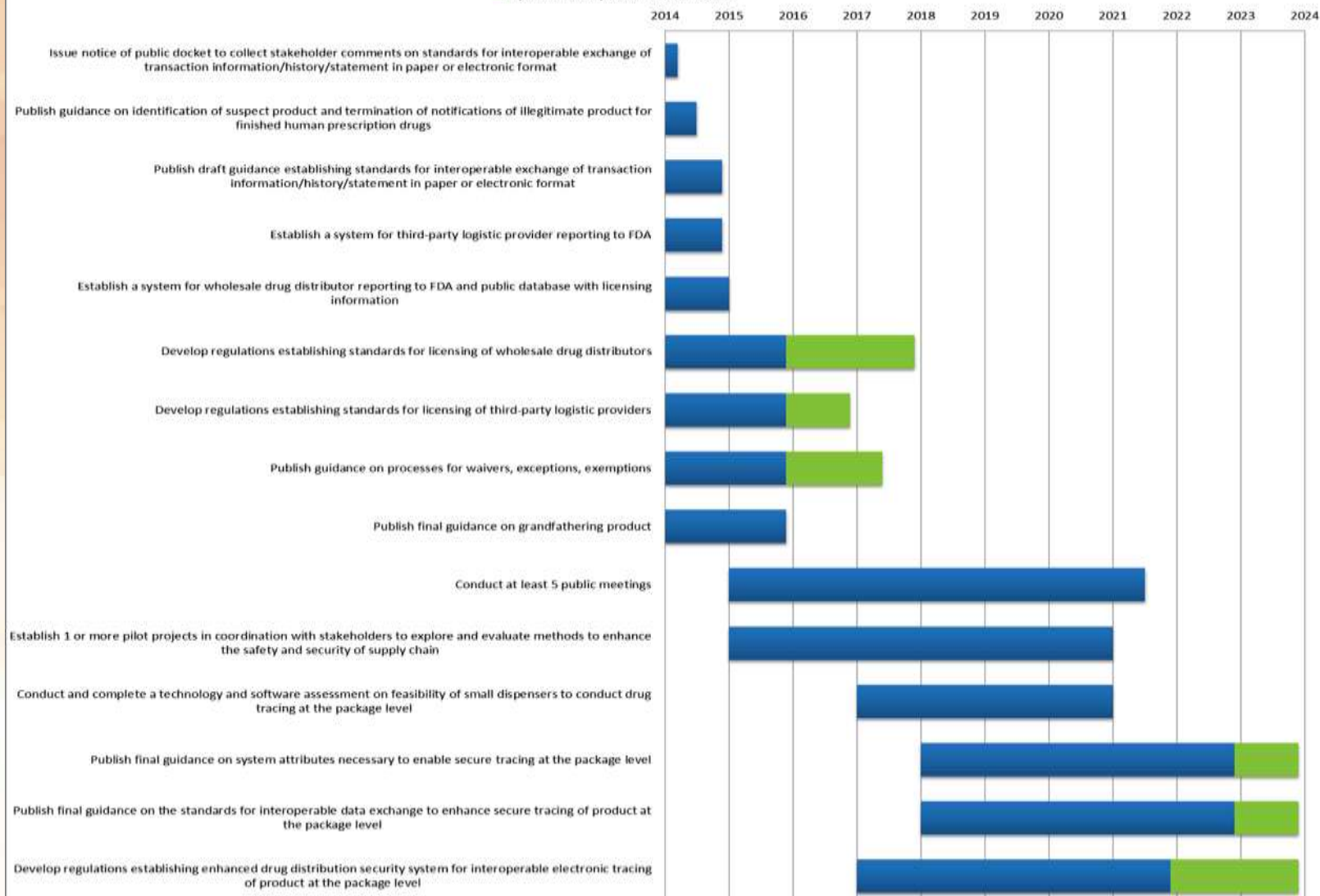


# Implementation Updates (1)

## Summary of Planned Implementation Timeframes for the Drug Supply Chain Security Act

Date of enactment: November 27, 2013

■ planned timeframes for FDA activity  
■ implementation period for stakeholders





# Implementation Updates (2)

## What is next?

- **Regulations – Standards for licensure (WD and 3PLs)**
- **Waivers, Exceptions, Exemptions**
- **Grandfathering product**
- **Product identification**
- **Pilot project(s)**
- **Public meetings or workshops**
- **Assessment of small dispensers**
- **Other...**



# What's next? (1)

## Wholesale Distributor and 3PL Licensure

- FDA is developing new federal standards for licensing of wholesale drug distributors and third-party logistics providers (3PLs) and a federal system for licensing for use when a state has not established licensure requirements.
- Effective dates for licensing regulations
  - Wholesale distributors: 2 years after finalized
  - 3PLs: 1 year after finalized



# What's next? (2)

- **Waivers, Exceptions, Exemptions**

- Waiver for any requirements of section 582 due to undue economic hardship or emergency medical reasons
- Exception from requirements of section 582 related to product identifiers if the package is unable to accommodate a label with sufficient space
- Exemption for other products or transactions from the requirements of section 582

- **Grandfathering**

Establishes whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements shall be exempted from the product identifier requirements of section 582



# What's next? (3)

## Product Identification

- **No later than 4 years (11/27/2017), manufacturers, followed by repackagers (11/27/2018) shall place a unique product identifier on certain prescription drug packages**
    - 2D bar code
  - **Product identifier**
    - National Drug Code
    - Serial number
    - Lot number
    - Expiration date
- 
- **After 6 years (11/27/2019), wholesalers, followed by dispensers (11/27/2020), will only trade products with product identifiers.**
  - **Verification requirements change once product is serialized.**





# Resources

## **FDA DSCSA web page:**

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

- Overview
- Implementation Plan
- Links to FDA webinar(s)
- Regulatory Documents (Guidances, FR notices...)

## **Questions about the DSCSA can be sent to:**

[drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov)

## **Questions about Wholesale Distributor or 3PL requirements can be sent to:**

[wdd3plrequirements@fda.hhs.gov](mailto:wdd3plrequirements@fda.hhs.gov)

# Questions?

Evaluation: [surveymonkey.com/s/GDF-D1S9](https://surveymonkey.com/s/GDF-D1S9)