

Drug Supply Chain Security Act (DSCSA): Implementation Updates

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U.S. Food and Drug Administration

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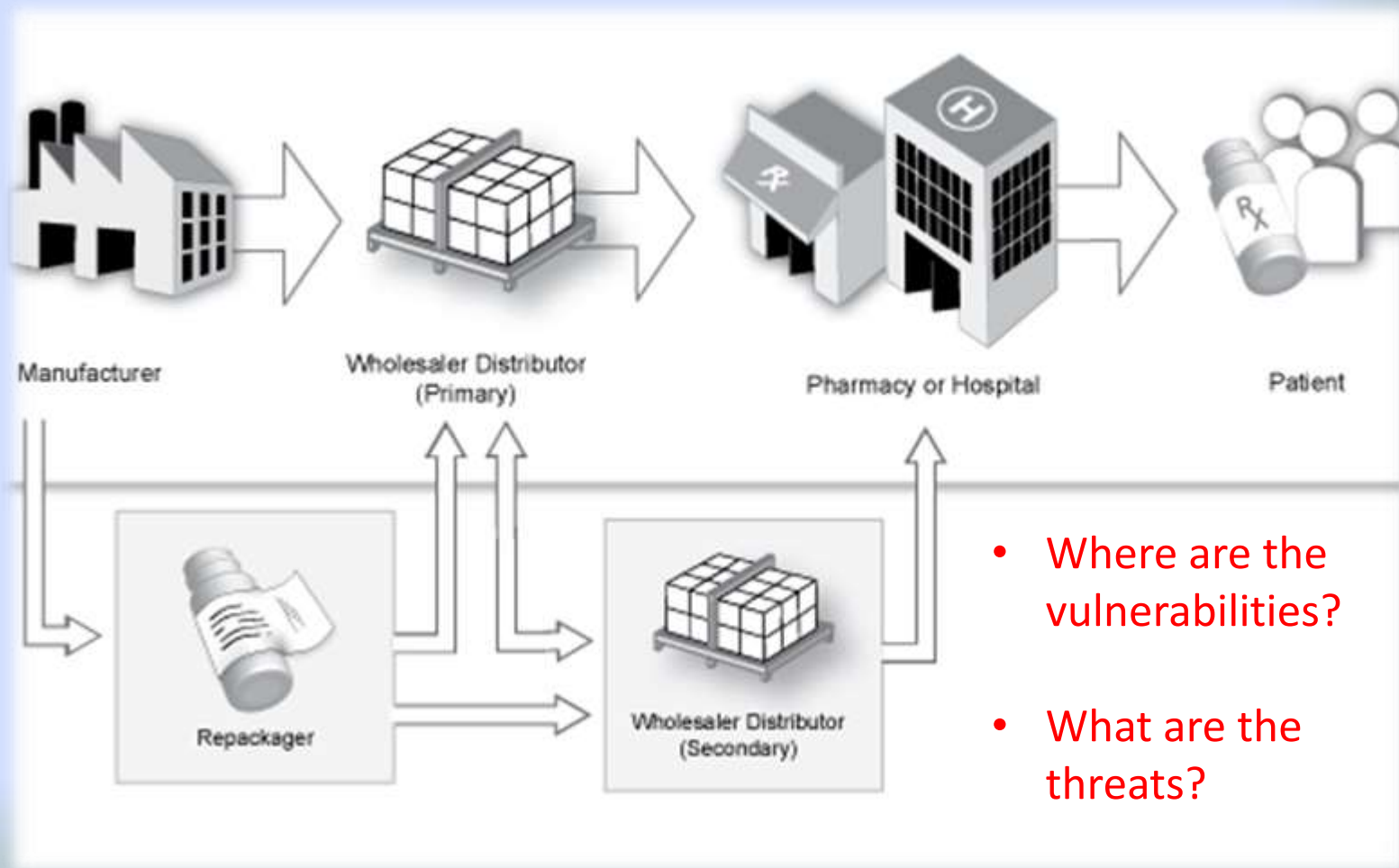
Disclaimer

The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice.

Additional Resources

Updates and links to FDA documents or notices summarized in this presentation can be found on the DSCSA webpage on FDA's website.

Supply Chain Security



- Where are the vulnerabilities?
- What are the threats?

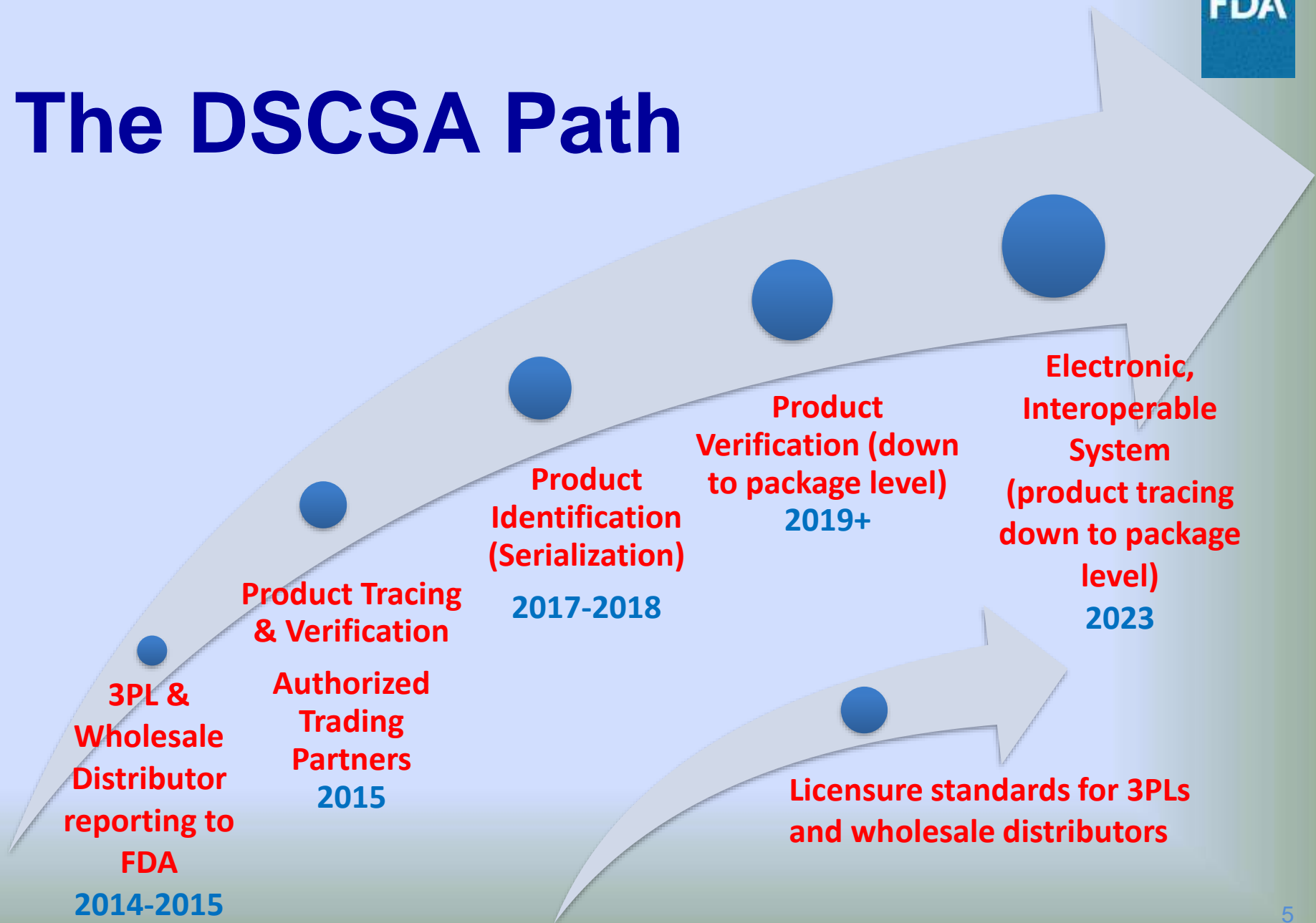
Overview of the DSCSA



Title II: Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal FD&C Act

- 581 – Definitions
- 582 – Requirements (product tracing, product identification, verification)
- 583 – Standards for licensure of WDs
- 584 – Standards for licensure of 3PLs
- 585 – Uniform national policy

The DSCSA Path



Scope of the law*

Product

- What's covered:
 - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- What's not covered:
 - Blood or blood components intended for transfusion
 - Radioactive drugs or biologics
 - Imaging drugs
 - Certain IV products
 - Medical gas
 - Homeopathic drugs
 - Lawfully compounded drugs

Transaction

- Transfer of product where a change of ownership occurs
- Exempt
 - Intracompany distributions
 - Distribution among hospitals under common control
 - Public health emergencies
 - Dispensed pursuant to a prescription
 - Product sample distribution
 - Blood and blood components for transfusion
 - Minimal quantities by a licensed pharmacy to a licensed practitioner
 - Certain activities by charitable organizations
 - Distributions pursuant to a merger or sale
 - Certain combination products
 - Certain medical kits
 - Certain IV products
 - Medical gas distribution
 - Approved animal drugs

**Refer to definitions in Section 581(13) for product and 581(24) for transaction for specific information regarding exclusions or exemptions.*

Product Tracing

- Beginning in 2015, manufacturers, repackagers and wholesale distributors, and dispensers (primarily pharmacies) are required to exchange information about a drug and who handled it each time it is sold in the U.S. market.
- For each transaction, “product tracing information” should be exchanged. Product tracing information consists of:
 - Transaction *information (TI)* (which includes lot number of product, except for certain wholesale drug distributor transactions)
 - Transaction *history (TH)*
 - Transaction *statement (TS)*
- Draft Guidance issued (11/2014): *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information* (paper or electronic formats)

Definitions: Transaction Information, History, and Statement

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.

Verification

- Beginning 2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) must have 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.

Definitions:

suspect and illegitimate product

- **Suspect Product** - reason to believe that product potentially:
 - counterfeit, diverted, stolen
 - subject of fraudulent transaction
 - intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans
- **Illegitimate Product** - credible evidence that the product actually is any of the above

Verification

Draft Guidance (6/2014): 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>

- Form FDA 3911: Drug Notification



Drug Notifications – Form FDA 3911

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved: OMB No. 0910-0806 Expiration Date: December 31, 2018 See PRA Statement on page 2.
Drug Notification		
<i>Refer to instruction sheet (Form FDA 3911 Supplement) for more information.</i>		
1. Type of Report (Select one): <input type="checkbox"/> Initial Notification <input type="checkbox"/> Follow-Up Notification <input type="checkbox"/> Request for Termination		
2. Incident Number (Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)		
3. Date of Initial Notification (mm/dd/yyyy)	4. Date Company Determined Product Was Illegitimate (mm/dd/yyyy)	5. Classification of Notification (Select from list) ▼
Description of Product		
6. Name of Product as It Appears on Label		
7. Primary Ingredients(s) (if known)		
8. Drug Use (Select from list) ▼	9. Drug Description (Select from list) ▼	
10. Strength of Drug	11. Dosage Form (Select from list) ▼	
12. Quantity of Drug (Number and Unit)	13. NDC Number (if applicable)	14. Serial Number (if applicable)
15. Lot Number(s)		
16. Expiration Date(s)		
17. For Notification: Description of Event/Issue		
Add Page for Item 17		
18. For Request for Termination of Notification: Description of why notification is no longer necessary		
Add Page for Item 18		
19. If you have submitted information to FDA through an alternative mechanism, check all that apply.		
<input type="checkbox"/> BPDR <input type="checkbox"/> MedWatch 3500 <input type="checkbox"/> None		
<input type="checkbox"/> FAR <input type="checkbox"/> MedWatch 3500A <input type="checkbox"/> Other (Specify): _____		
FORM FDA 3911 (12/15) Page 1 of 2		

Company/Facility Information	
20. Company Name & Address	
Name	
Address 1 (Street address, P.O. box, etc.)	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City	State/Province/Region
Country	ZIP or Postal Code
21. Company Category (Select from list) ▼	
22. Unique Facility Identifier (of company named in #20) ▼	
23. Contact Information (Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)	
Name	Telephone Number (Include area code)
Email Address	
SUBMIT BY EMAIL	
<p style="text-align: center;">A willfully false statement is a criminal offense, pursuant to U.S. Code, title 18, section 1001.</p>	
<p style="text-align: center;">This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p style="text-align: center;">*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p style="text-align: center;">The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <p style="text-align: center;">*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*</p>	
FORM FDA 3911 (12/15) Page 2 of 2	

Confirm authorized trading partners

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 logistics providers:** 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

Public Workshop on Proposed Pilot Project(s) under the DSCSA

- April 5-6, 2016
- Over 100 attendees from across the supply chain
- Group discussions were webcasted
- Goals of the workshop: to discuss
 - pilot project objectives
 - evaluation methods
- Slides and summary are posted at our public workshop webpage:

<http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm>

Wholesale Distributor and Third-party Logistics Provider Requirements

Report Licensure to FDA (3PLs and Wholesale Distributors)

Who	When	Frequency	What
3PL	Started 11/27/2014	annually	Licensing status and contact information
WDD	Started 1/1/2015	annually	Licensing status, contact information, significant disciplinary actions

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
- Public docket comments are under review

WDD and 3PL Reporting Database

Public data

The [Wholesale Distributor and Third-Party Logistics Provider Reporting Database](#) contains information submitted by wholesale distributors and third-party logistics providers (3PLs).

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.

The wholesale distributor and 3PL reporting database will be updated on a daily basis.

Download and Search

- [Wholesale Distributor and Third-Party Logistics Provider Reporting Database Download file. \(XLSX - 853KB\)](#)
- [Wholesale Distributors and Third-Party Logistics Providers Search](#)

This information is submitted to FDA to comply with the reporting provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and additional information is submitted voluntarily.

Wholesale distributors and 3PLs are required to report licensure and certain other information for each facility annually to FDA under FD&C Act section 503(e)(2) and section 584 respectively.

The information included in the database is self-reported by wholesale distributors and 3PLs. Changes to the information can only be made by the entity reporting the information, who must resubmit the information to the FDA. Reporting by a wholesale distributor or 3PL does not denote that the facility is licensed or approved by FDA or that the firm and facility is in compliance with applicable State and Federal laws and regulations.

Annual reporting by wholesale distributors and 3PLs can be made using FDA's CDER Direct Electronic Submissions Portal at https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP. If a company determines that it has reported in error, please e-mail wdd3plrequirements@fda.hhs.gov

WDD and 3PL Reporting Database

[Home](#) > [Drug Databases](#) > [WDD/3PL Home](#)

Wholesale Distributor and Third-Party Logistics Providers Reporting

[About this Database](#)

Please search using at least one criterion below.

Facility Name:

Facility Type:

All



Facility Address (State):

Select location



Facility License (State):

Select license state



Search

Reset

What's Next

Product Identification (Serialization)

- A unique product identifier must be placed on certain prescription drug packages
 - Manufacturers (No later than 11/27/2017)
 - Repackagers (No later than 11/27/2018)
- Product identifier consists of
 - National Drug Code
 - Serial number
 - Lot Number
 - Expiration Date
- Data Carrier – 2D bar code

Standardized
numerical
identifier



After Products are Serialized

- Only buy and sell products encoded with product identifiers *(unless grandfathered under section 582(a)(5))*
 - Repackagers (beginning 11/27/2018)
 - Wholesale distributor (beginning 11/27/2019)
 - Dispensers (beginning 11/27/2020)
- Verification product at the package level, including the standardized numerical identifier *(NDC and serial number)*
**see respective sections of 582 for specific verification requirements*
 - Manufacturers: starting 11/27/2017
 - Repackagers: starting 11/27/2018
 - Wholesale distributors: starting 11/27/2019
 - Dispensers: starting 11/27/2020
- Enhanced product tracing by 2023 at the package-level



Public Meeting: Progress Toward Implementing the Product Identification Requirements of the DSCSA

- October 14, 2016
- FDA wants to learn about efforts underway to implement product identification requirements, including the use of product identifiers to enhance tracing at the product level
- Will be webcasted
- Register by October 6, 2016
- Request to present at the public meeting by October 5, 2016

<http://www.fda.gov/Drugs/NewsEvents/ucm519587.htm>

DSCSA Pilot Project(s) under Section 582(j) of the FD&C Act

- FDA shall establish 1 or more pilot projects
- Coordinate with manufacturers, repackagers, wholesale distributors and dispensers
- Explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- Design: utilization of product identifiers for product tracing and verification, improve technical capabilities needed to utilize product identifiers, identify system attributes that are necessary, other

Standards for Licensure of Wholesale Distributors and 3PLs

- FDA is developing new federal standards for licensing of wholesale drug distributors and third-party logistics providers 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

Enhanced System – 2023

- Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 years after enactment of this Act, including those relating to:
 - Electronic exchange of transaction information for each sale of certain prescription drugs
 - Verification of product identifiers at the package level
 - Prompt response to suspect and illegitimate products when found
 - Improved efficiency of recalls

Resources

FDA DSCSA web page:

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

- Overview
- Implementation Plan
- Links to FDA webinar(s) and public workshops/meetings
- Regulatory Documents (Guidances, FR notices...)

FDA Readiness Checklist:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm>

QUESTIONS?



Please complete the session survey:

surveymonkey.com/r/DRG-D1S6

