The Global Language of Business

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U.S. Food and Drug Administration

USA Drug Supply Chain Security Act (DSCSA) Requirements and Implementation Plans

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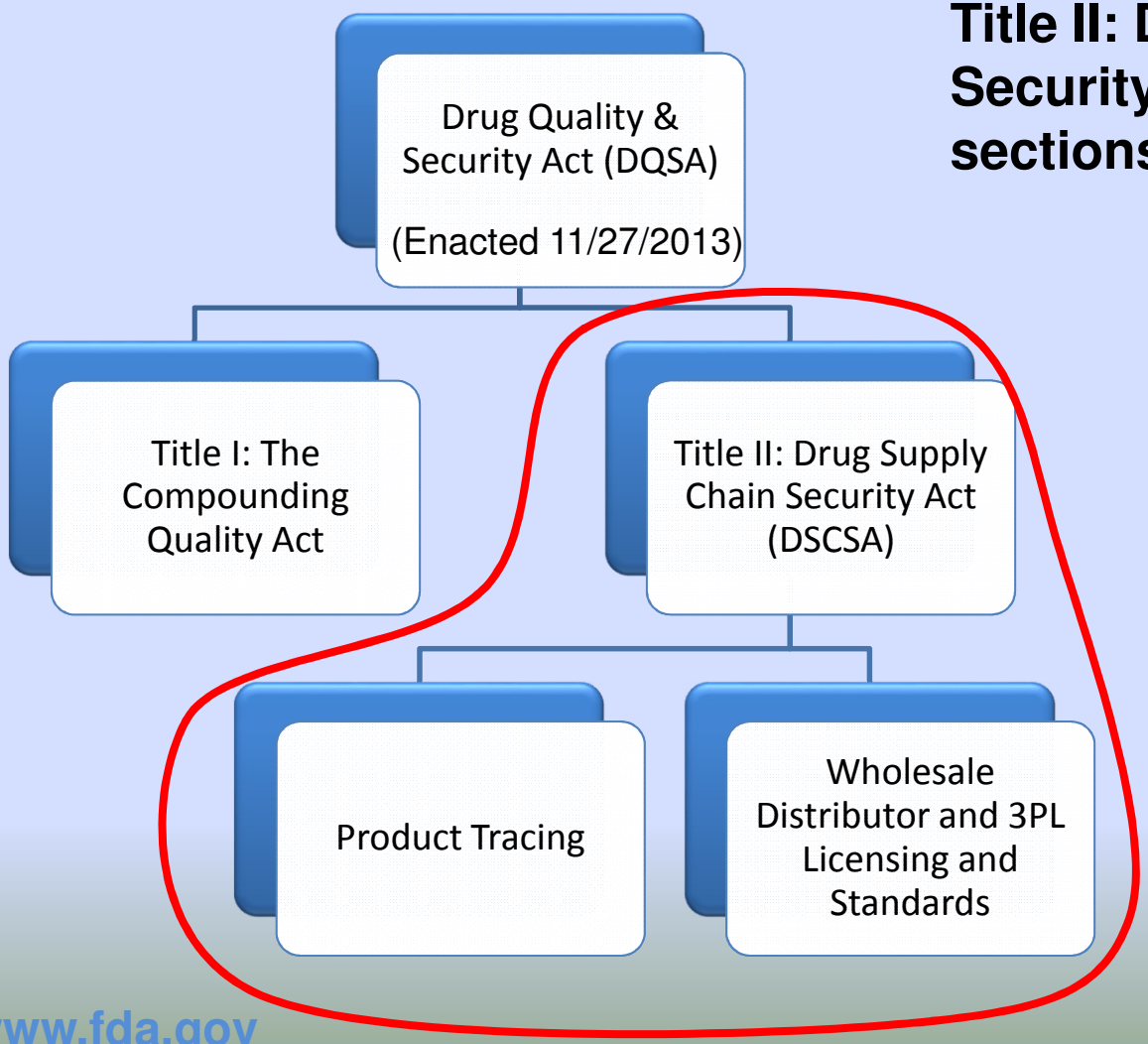
Disclaimer

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.

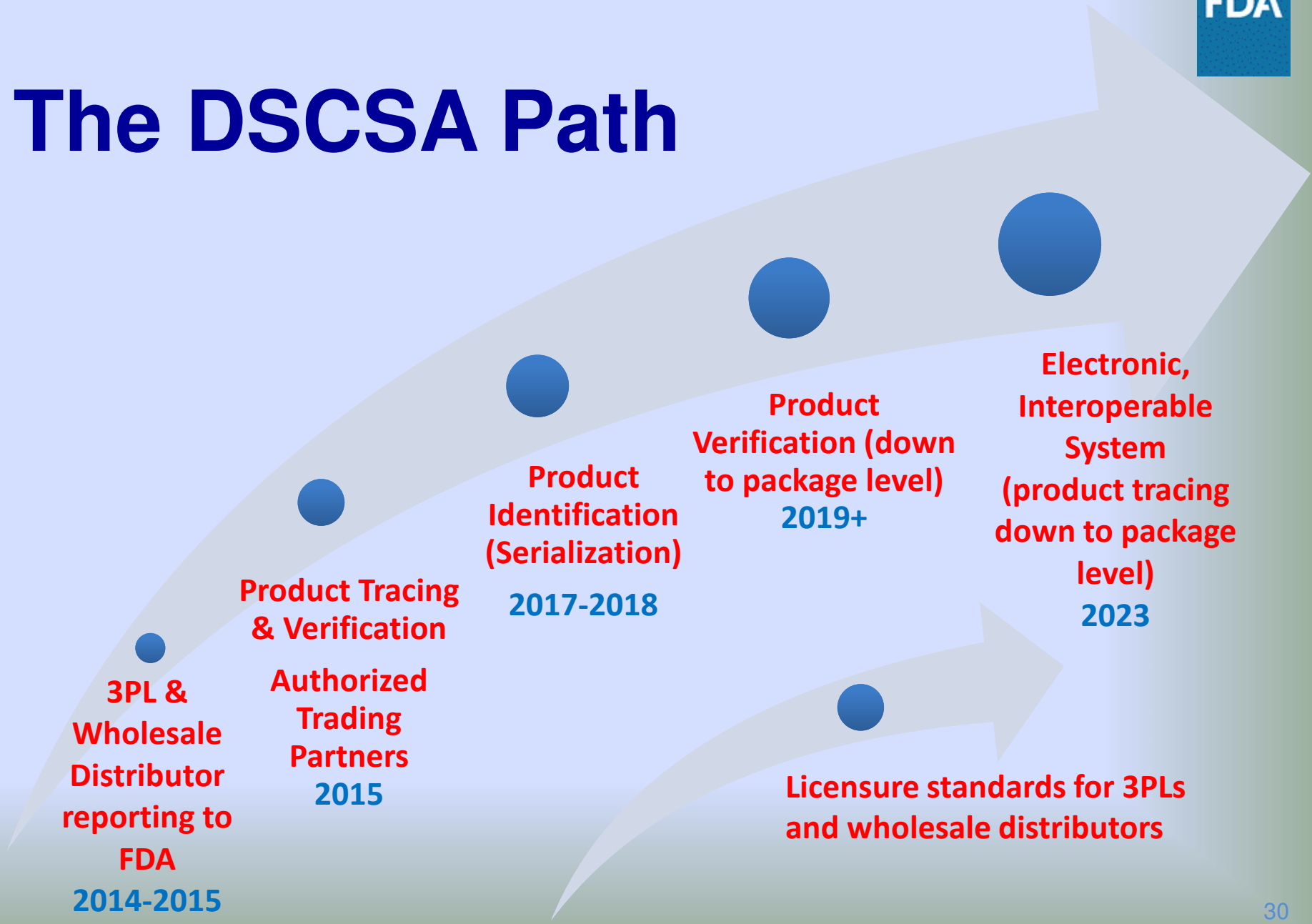
Overview of the DSCSA



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 wholesale distributors
- 584 – Standards for licensure of third-party logistics providers (3PL)
- 585 – Uniform national policy

The DSCSA Path



Wholesale Distributor and Third-party Logistics Provider Requirements

Report Licensure to FDA by Third-Party Logistics Providers (3PL) and Wholesale Distributors(WDD)

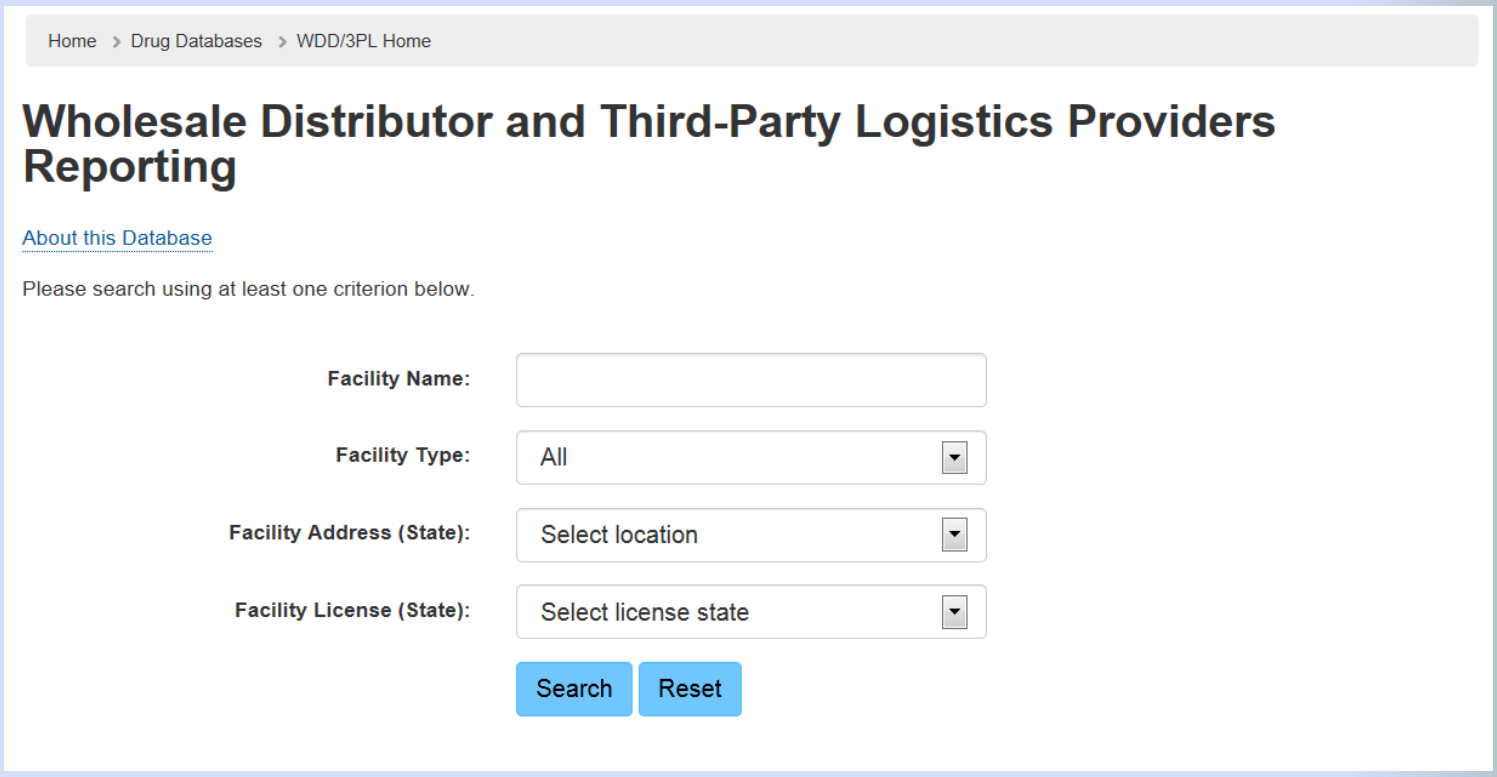
Who	When	Frequency	What
3PL	Started 11/27/2014	Annually (January 1 – March 31)	Licensing status and contact information
WDD	Started 1/1/2015		Licensing status, contact information, significant disciplinary actions

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

Wholesale Distributor and 3PL Reporting Database



- Self-reported information (licensing status, contact information, significant disciplinary actions) by each wholesale distributor and 3PL
- Searchable database or download the file

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

Product Tracing, Verification, and Authorized Trading Partner Requirements

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

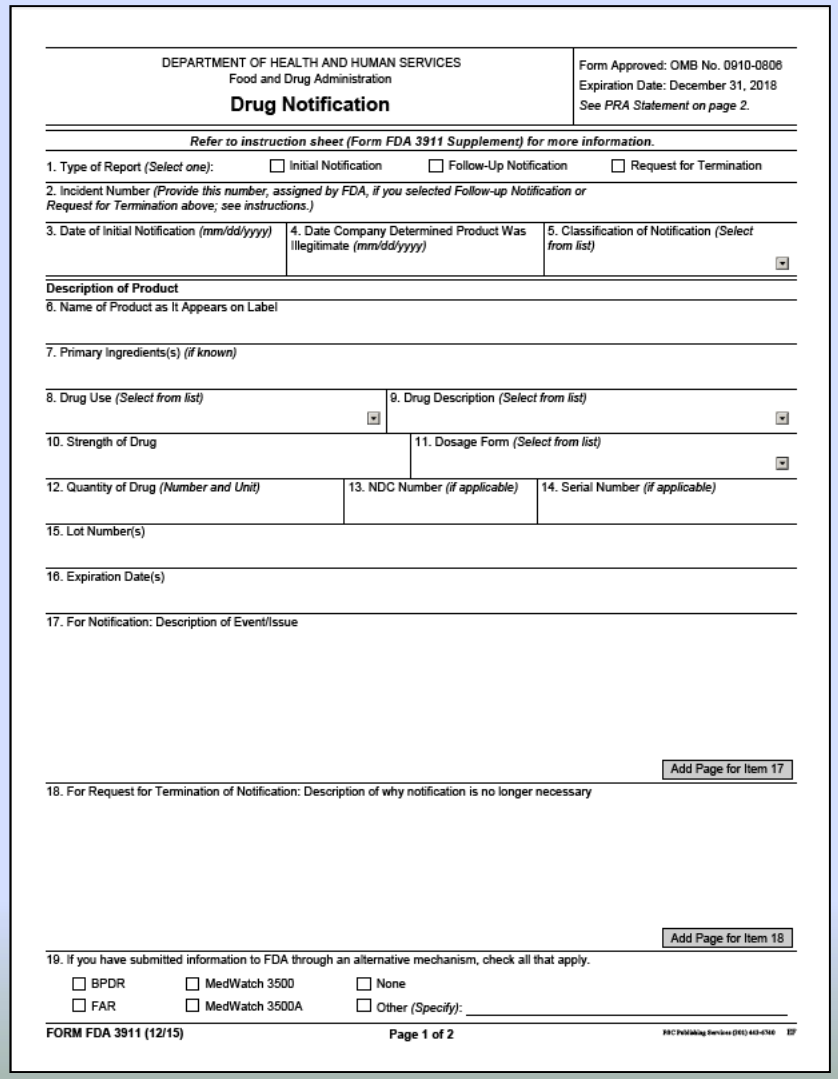
Draft Guidance (6/2014): Identification of Suspect Product and Notification

- 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 (now a fillable form)

Drug Notifications – Form FDA 3911



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ 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

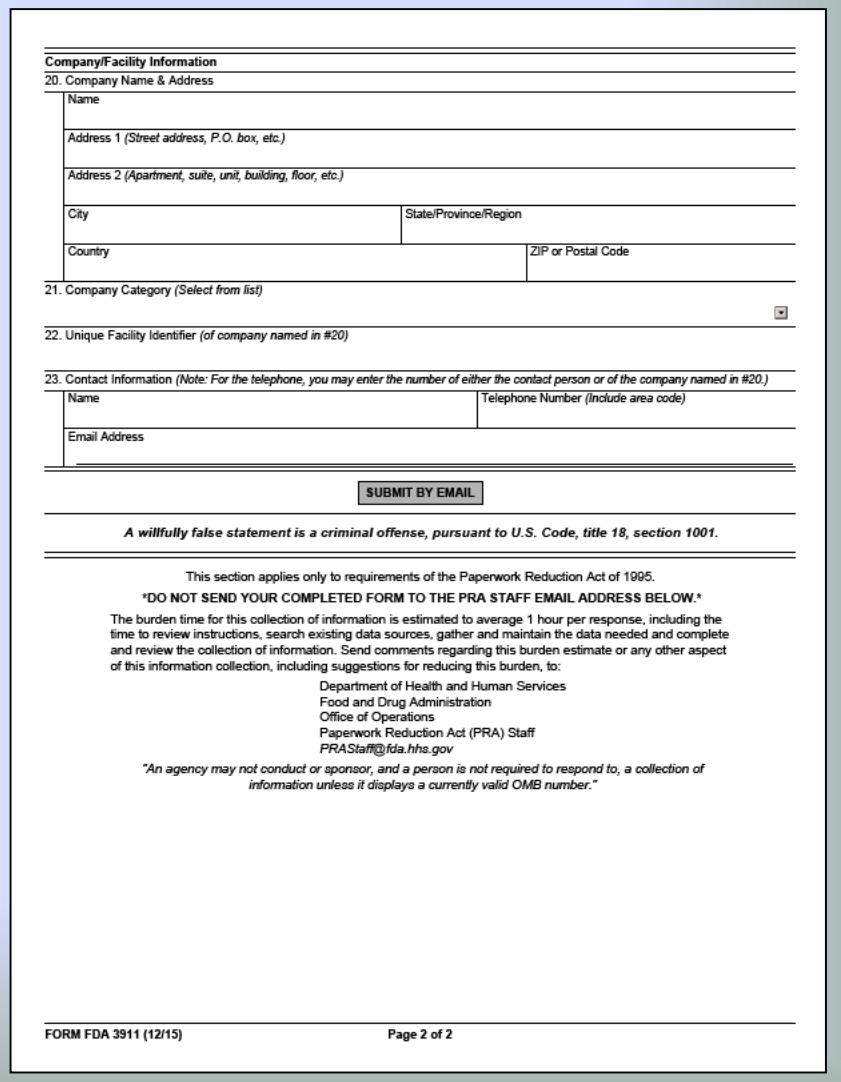
18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ 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

A willfully false statement is a criminal offense, pursuant to U.S. Code, title 18, section 1001.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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

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

Standardized numerical identifier

- Data Carrier – 2D data matrix bar code

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

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

Public Workshop:
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

Focus of FDA Pilot Project(s)

- Assess the ability of supply chain members to:
  - satisfy the requirements of section 582
  - to identify, manage, prevent the distribution of suspect and illegitimate drugs
- Identify the system attributes needed to accomplish the requirements of section 582 (particularly utilizing a product identifier for product tracing or verification)
- Demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain
- FDA will coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors.

The Information above represents stakeholder feedback FDA received at the public workshop on "Proposed Pilot Project(s) under the Drug Supply Chain Security Act" and through the public docket. This information should not be interpreted as a final decision or position of FDA.

General Considerations for Pilot Projects

- Ensure an adequate mix of products and packaging levels
- Include all stakeholders (types and sizes) and different transactions
- Keep pilot project flexible (different partners, evolving scenarios, additional use cases and special scenarios)
- Risk-based approach to determine what to pilot (e.g., target known weaknesses in the supply chain)
- Timing of pilots, to make them useful as trading partners implement requirements
- Metrics should focus on end-to-end supply chain and also specific operations
- Use initial pilots to identify other pilots based of severity or frequency of issue(s) encountered
- Simulate illegitimate products/transactions to test a process or system
- Document costs to implement, use, and maintain piloted solutions
- Document experience level and role of pilot partners doing the piloted activities – enables comparison of results from high and low experience partners

The Information above represents stakeholder feedback FDA received at the public workshop on "Proposed Pilot Project(s) under the Drug Supply Chain Security Act" and through the public docket. This information should not be interpreted as a final decision or position of FDA.

Proposed Pilot Project Objectives (examples)

- Product identification (imprinting/affixing, management of serial numbers)
- Bar Code Quality (readability)
- Interoperability (processes or systems)
- Data/Database/System Issues (performance measures, access, etc.)
- Aggregation/Disaggregation (when to aggregate data, use of inference)
- Verification/Notification (communications)
- Exceptions/Errors/Inconsistencies (over or under shipments)

The Information above represents stakeholder feedback FDA received at the public workshop on "Proposed Pilot Project(s) under the Drug Supply Chain Security Act" and through the public docket. This information should not be interpreted as a final decision or position of FDA.

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

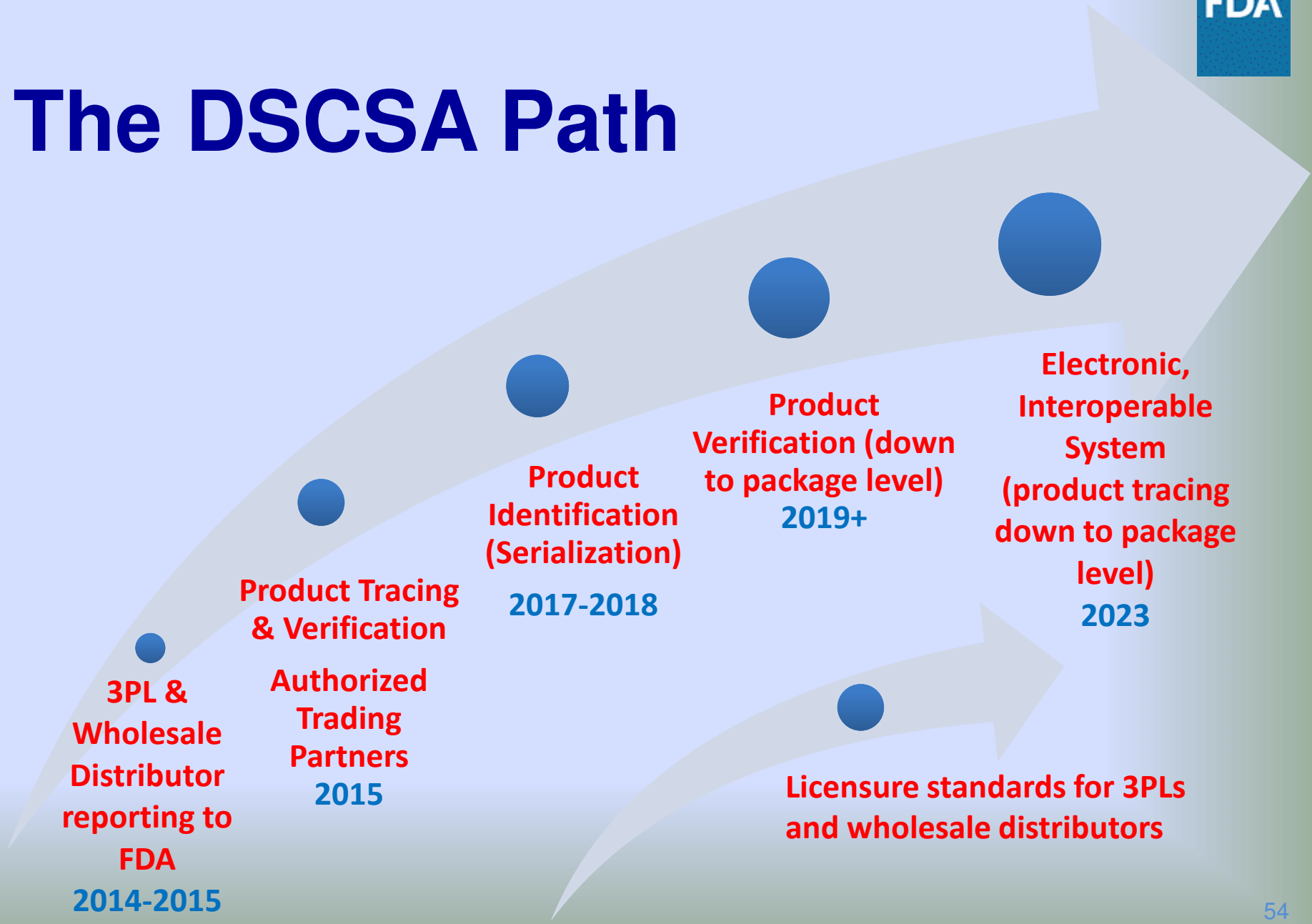
- October 14, 2016
- About 150 attendees
- 10 oral presentations by stakeholders
- Recorded webcast and slides will be posted
- Submit comments to the public docket:
  closes Nov. 14, 2016

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

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

- FDA wants to learn about industry efforts underway to implement product identification requirements, including the use of product identifiers to enhance tracing at the product level.
- This includes best practices in each sector of the pharmaceutical distribution supply chain to conduct product tracing, verification, and product identification.
- This may include the processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

The DSCSA Path



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…)

Public Meeting webpage: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

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