U.S. FOOD & DRUG ADMINISTRATION



Drug Supply Chain Security Act

Implementation Track and Trace Issues in 2017

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November 15, 2017

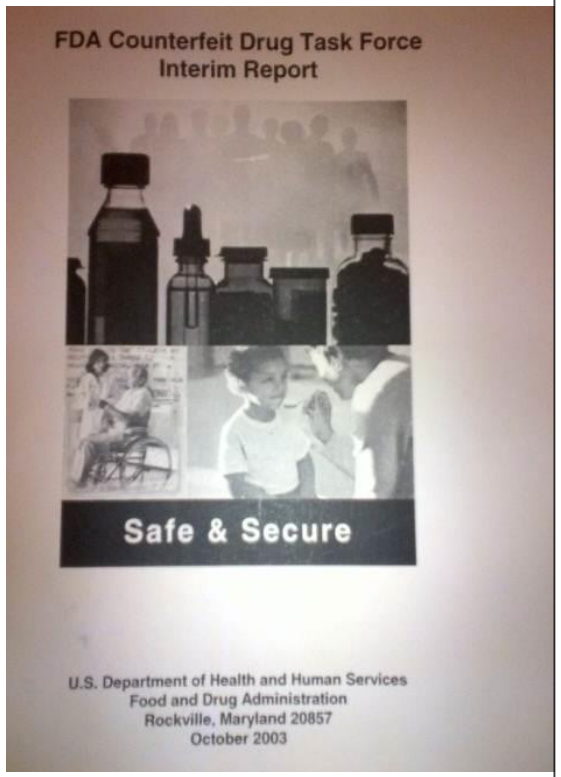
Overview

DSCSA

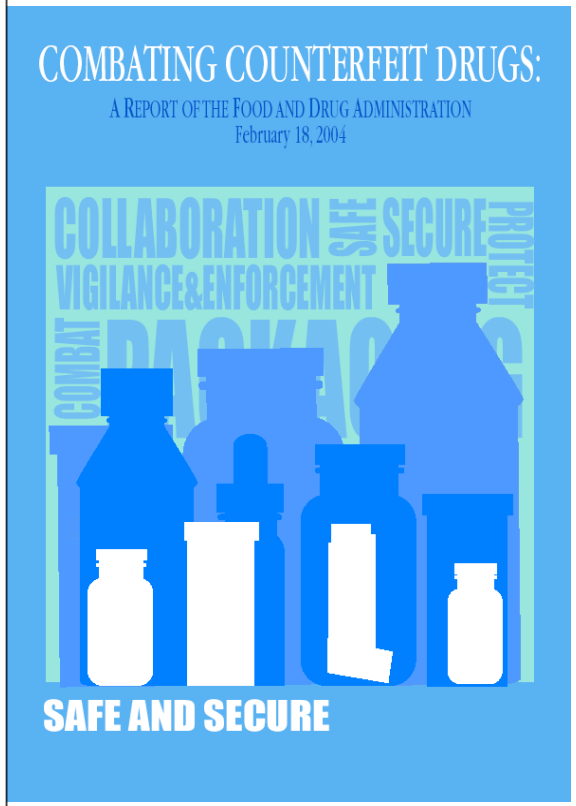
- Where we are now
- Where we need to go

Global track and trace activities

FDA past track and trace efforts



2003 -- FDA Counterfeit Drug Task Force established
2003 -- Interim Report
2004 -- Final Report
--recommended track and trace technologies, including mass serialization
2005 -- Report Update
--progress towards electronic track and trace, but more work to be done
2006 – Report Update
-- continued momentum and interest, but slow progress toward goal
2010 – Guidance
-- established voluntary standards for product identification



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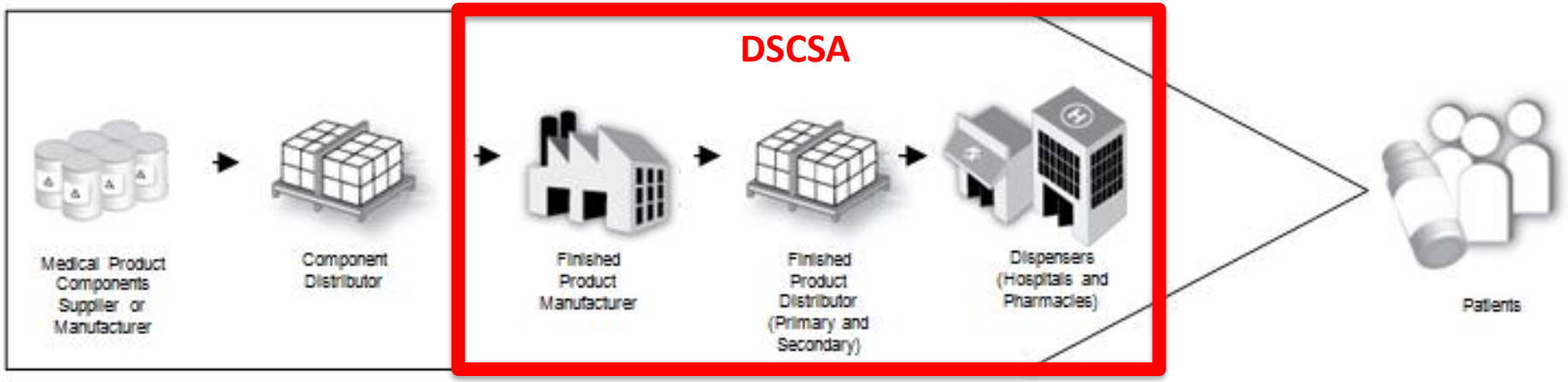
Pharmaceutical Supply Chain



Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

Protect the product → **Protect the patient**

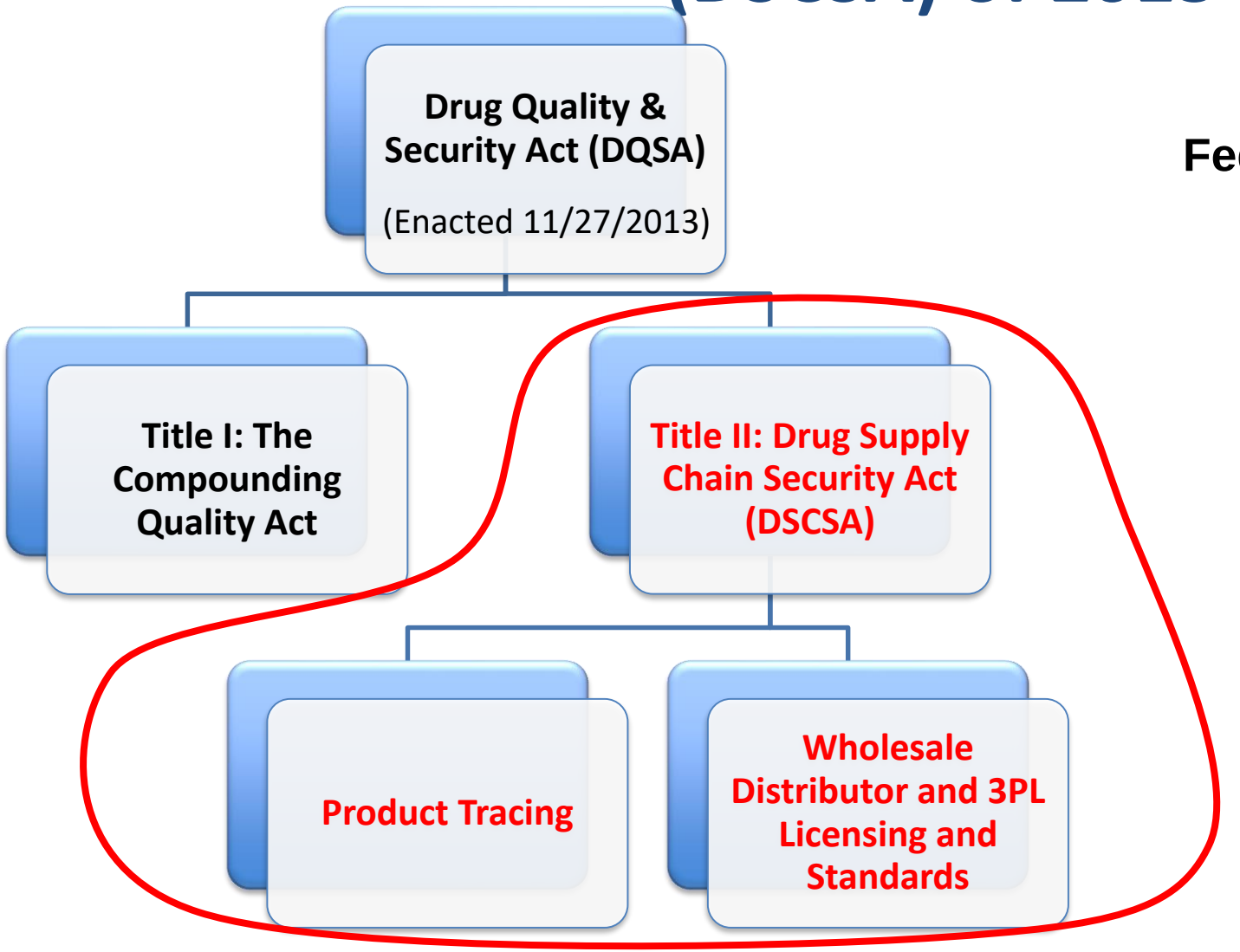
Goals of the DSCSA

Develop an electronic, interoperable system by 2023 to identify and trace certain prescription drugs as they move through the U.S. supply chain.

- *The new system will:*
  - facilitate the exchange of information by trading partners at the individual package level
  - improve efficiency of recalls
  - enable prompt response to suspect and illegitimate products when found
  - create transparency and accountability in the drug supply chain

Establish national standards for licensure for wholesale distributors and third-party logistics providers.

The Drug Supply Chain Security Act (DSCSA) of 2013



Federal FD&C Act Sections:

- 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

Drug Supply Chain Security Act (DSCSA)

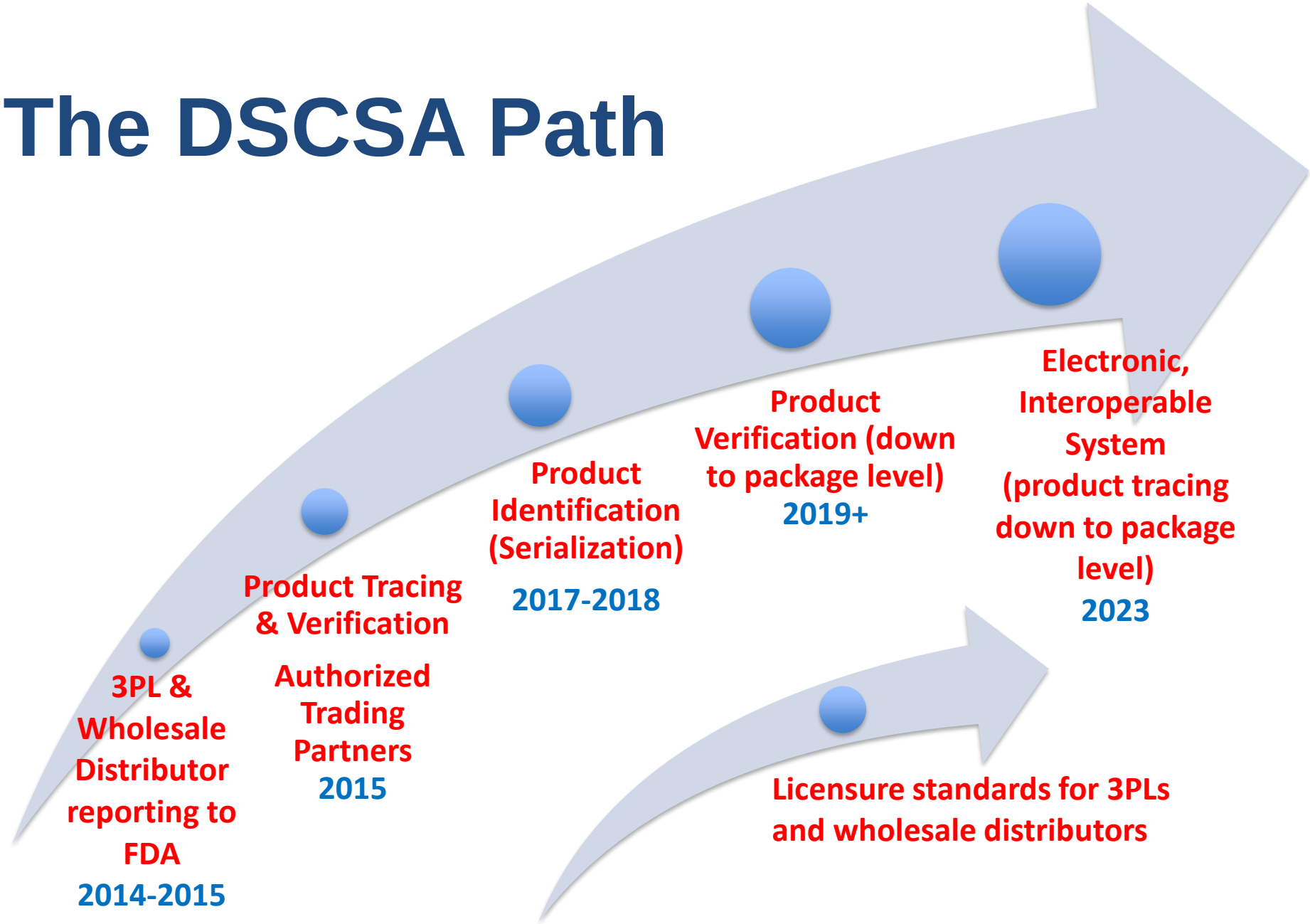
Product Tracing

Verification

Product Identification (Serialization)

Wholesale Distributor and 3PL Licensing Standards

The DSCSA Path



Where are we now: WD/3PL reporting

- We have a single national database
- Self-reported information by wholesale distributors (WD) and third-party logistics providers (3PL)
- Search and file download capability
- Annual Reporting Q&A Guidance
- ***NEXT REPORTING PERIOD: January 1, 2018 –March 31, 2018***

Where are we now: Product tracing

Trading partners exchange information

Lot-level

Paper or electronic formats

OIG Report: Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information

- Almost ½ exchanged most, but not all, required elements
- Wide variety of transmission modes and formats

Where we are now: Verification

- Systems and processes to respond to verification requests for suspect product
- Quarantine and investigate suspect product to determine if illegitimate product
- Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
- Respond to notifications of illegitimate product
- Identification of suspect product and notification guidance

Identification of Suspect Product and Notification (final guidance)

Describes scenarios that increase risk of suspect product for entering supply chain

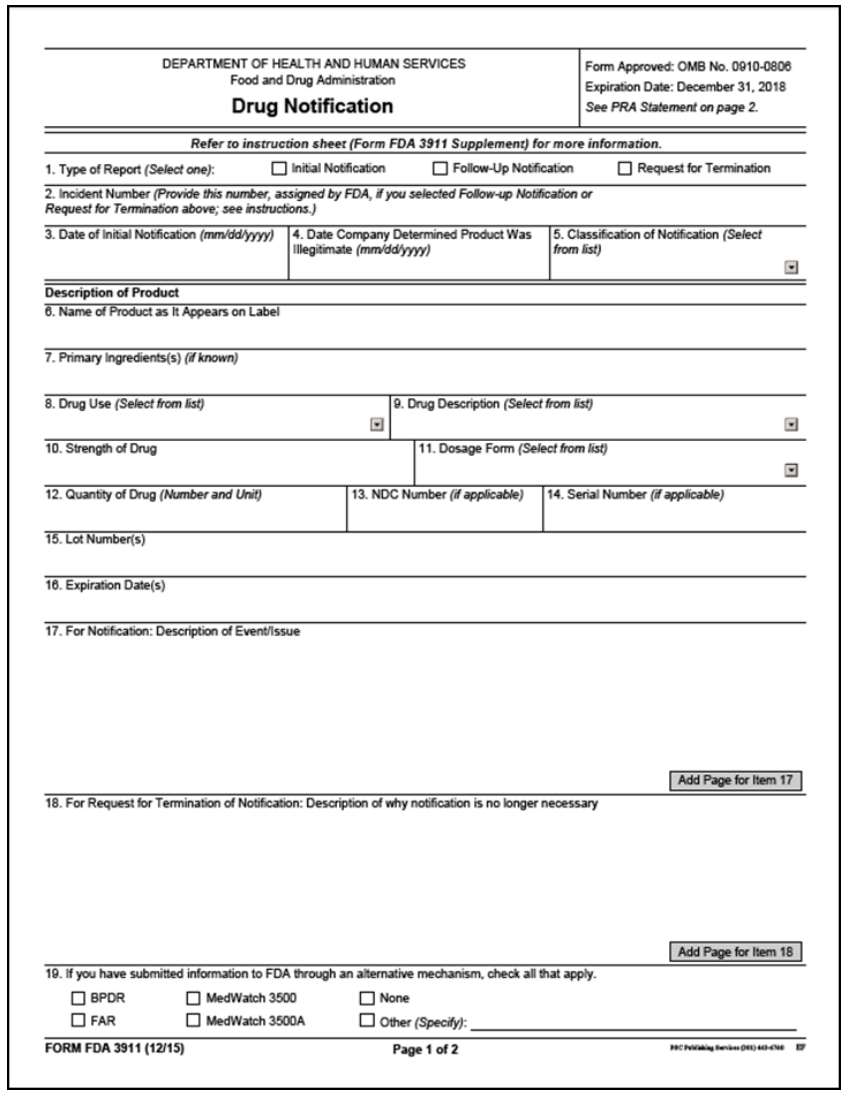
Recommendations on how to identify and make determination of suspect product

Sets forth process to notify FDA and consult with FDA to terminate notifications about *illegitimate product*

Form FDA 3911 Drug Notification

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf (A portion of the guidance is not final and comments are being considered.)

Notify FDA of illegitimate products



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

Required to:

- **Notify FDA of illegitimate product within 24 hours of determination (must also notify other trading partners**).
- Consult with FDA that a notification is no longer necessary to request termination of notification.

Who must notify?:

- Dispensers (primarily pharmacies)
- Manufacturers
- Repackagers
- Wholesale distributors

http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

Where are we now:
Authorized trading partners

- Manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers
- Appropriate registration with, or licensure from, FDA or State authorities, as applicable
- Can only do business with authorized trading partners
- Identifying Trading Partners Draft Guidance

Identifying Trading Partners Draft Guidance

Manufacturers	• Manufacturing establishments, application holders, co-licensed partners, affiliates
Repackagers	• Not a pharmacy solely engaged in packaging and labeling for an identified individual patient after receipt of a valid prescription
Wholesale distributors	• Differences in the definition of wholesale distribution in PDMA and DSCSA; some entities are now 3PLs
3PLs	• "other logistic services" • Not 3PLs: brokers, solution providers, common carriers…
Dispensers	• No product tracing requirements if product is dispensed to a patient or if it is a dispenser to dispenser sale to fulfill a specific patient need

Where are we now:
Product identification (Serialization)

A unique product identifier must be placed on certain prescription drug packages in human- and machine-readable formats

- Manufacturers (Under Draft Compliance Policy: No later than 11/27/2018)
- 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 barcode

Product Identifier -- Draft Compliance Policy

One year delay in enforcement of manufacturers requirement to affix or imprint product identifier on package or homogenous case

Need a product identifier for packages/homogenous cases intended to be introduced into a transaction into commerce on or after November 27, 2018

Verification: Enforcement discretion for trading partners who do not verify product that was introduced into a transaction into commerce without a product identifier between 11/27/17 and 11/26/18 without a product identifier.

Public comments under review

Where are we now:
Proposed DSCSA Pilot Program

FDA shall establish 1 or more pilot projects and 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

Public comments under review

Focus of FDA Pilot Program

Assess the ability of supply chain members to:

- satisfy the product tracing and verification requirements
- to identify, manage, prevent the distribution of suspect and illegitimate drugs

Identify the system attributes needed to accomplish the product tracing and verification requirements

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.

Drug Supply Chain Security Act

Drug Supply Chain Security Act Law and Policies

Are you ready for the Drug Supply Chain Security Act?

Drug Supply Chain Security Act Public Meetings

Drug Supply Chain Security Act Webinars and Presentations

Drug Supply Chain Security Act Resources for State Officials

Public Health Emergencies and DSCSA Requirements

When the Secretary of Health and Human Services declares a public health emergency under section 319 of the Public Health Service Act, there may be a need to facilitate the effective distribution of prescription drugs under emergency conditions. FDA is committed to ensuring that U.S patients receive needed medications during these situations.

A public health emergency is considered an "emergency medical reason" under the Drug Supply Chain Security Act (DSCSA). Upon declaration of a public health emergency, certain activities are automatically excluded through the time period of the declaration. Notably, product distribution for such emergency medical reasons is excluded from the DSCSA definitions of "transaction" and "wholesale distribution." Therefore, the DSCSA requirements related to product tracing and wholesale distribution do not apply to trading partner activities that address the public health emergency declaration. All other DSCSA requirements apply.

Entities engaged in these distribution activities should maintain the security of the supply chain as these prescription drugs are distributed to address the urgent public health need. When the public health emergency declaration expires, all DSCSA requirements apply.

Public health emergency declarations last until the Secretary declares that the public health emergency no longer exists or expires 90-days after the date of the declaration, whichever occurs first. The Secretary may extend the public health emergency declaration for subsequent 90-day periods for as long as the public health emergency continues to exist, and may terminate the declaration when the Secretary determines that the public health emergency no longer exists. Information about whether a declaration exists can be found at www.phe.gov.

Where do we need to go:
Enhanced Drug Distribution Security – 2023

Package level requirements for the interoperable, electronic tracing of products go into effect on November 27, 2023, 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

FDA Public Meeting Series

Enhanced drug distribution security under DSCSA

Stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA

3 public meetings

Dates	Topics
August 23, 2017	• Supply chain security in 2023 • Enhanced drug distribution security needs
December 5-6, 2017	• Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system

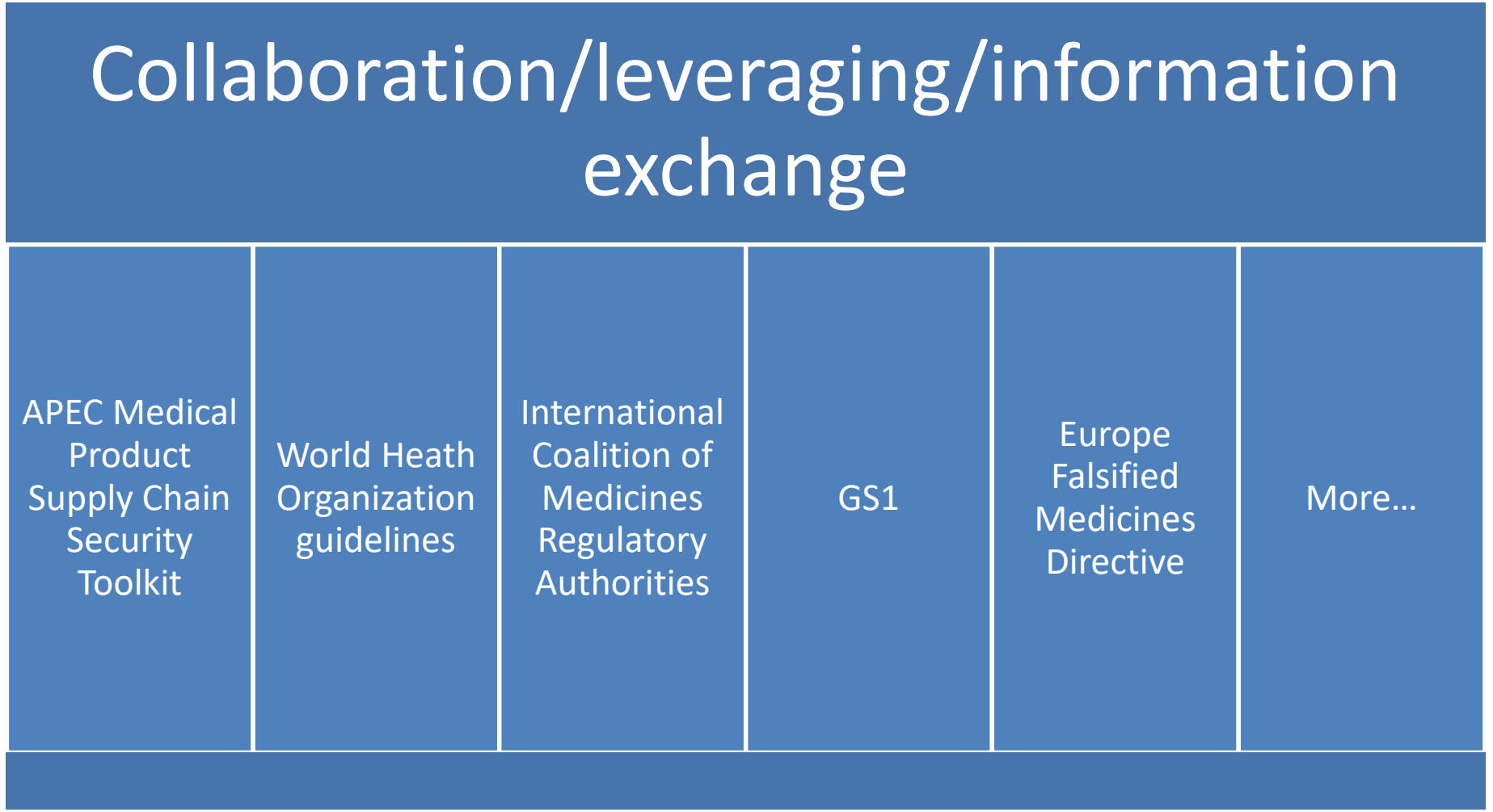
Vision of the 2023 enhanced drug distribution system

- Provide increased public health benefits
- Ensure diligence and vigilance by all trading partners
- Support FDA's compliance and enforcement efforts
- Be adaptable and flexible
- Longer term…Be compatible with the health care system and global marketplace

DSCSA: Guidances and regulations on the horizon

- Grandfathering
- Standardization of data and documentation practices for product tracing
- Product Identifier – Q&A
- Verification systems
- Waivers, exceptions, and exemptions
- WD/3PL licensing and standards proposed rule
- Finalize drafts…

Global track and trace activities



Product Tracing

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Resources

FDA DSCSA web page:

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

Questions about the DSCSA can be sent to:

drugtrackandtrace@fda.hhs.gov

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

wdd3plrequirements@fda.hhs.gov

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DISCLAIMER: Some requirements and statutory deadlines were paraphrased in these slides for presentation purposes and this presentation is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice. Please refer to the appropriate guidances, regulations, or law for specific information.

www.fda.gov

THANK YOU!