Drug Supply Chain Security Act (DSCSA) Implementation Update - 2018

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U.S. Food and Drug Administration
FDLI DQSA Conference -- 12/4/18

Objectives

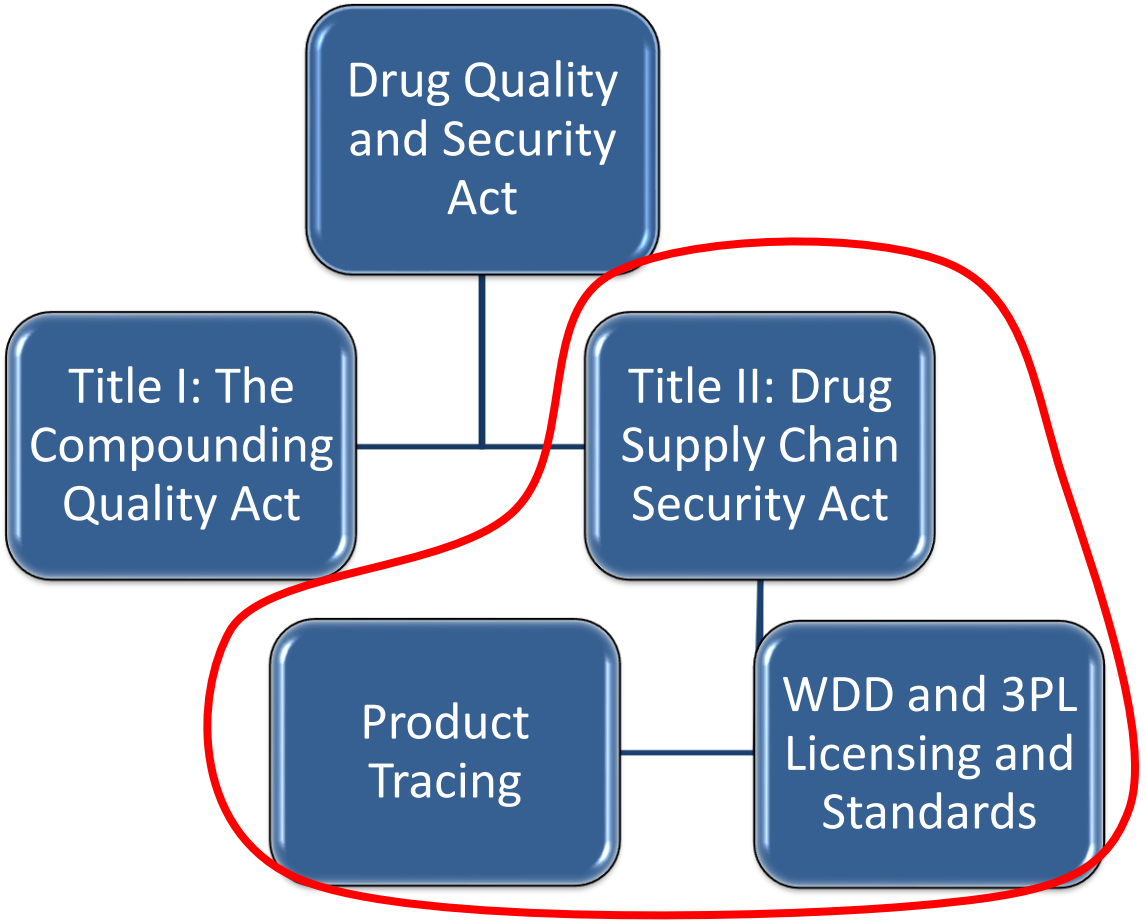
- Traceability implementation
  - Current
  - 2023
- Program updates
- Other news

Drug Compliance & Enforcement


Offices of the United States Attorneys United States Department of Justice
THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT of MONTANA
FOR IMMEDIATE RELEASE
Canadian Drug Firm Admits Selling Counterfeit an
Misbranded Prescription Drugs Throughout th
States
6 Canadians arrested in U.S. extradition request for allegedly selling fake cancer drugs online
CanadaDrugs.com founder, 5 others accused of illegally import
counterfeit drugs to doctors in U.S.
Karen Pauls · National Reporter · CBC News
June 19, 2017
cond Turkish man sentenced for smuggling counterfeit cancer drugs
Other business partner in drug wholesaling scheme was sentenced in October 2014
of Virginia
Friday, May 9, 2014
ompany Gallant Pharma And Co-Founder Sentenced
Counterfeit Version of Avastin in U.S. Distribution
SHARE TWEET LINKEDIN PIN IT EMAIL PRINT
Statement Update Issued: July 10. 2012
Protecting our supply chain protects patients!

Overview of the DSCSA

Title II: Drug Supply Chain Security Act (DSCSA) adds new sections in the Federal Food, Drug and Cosmetic Act (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 (3PLs)
- 585 – Uniform national policy

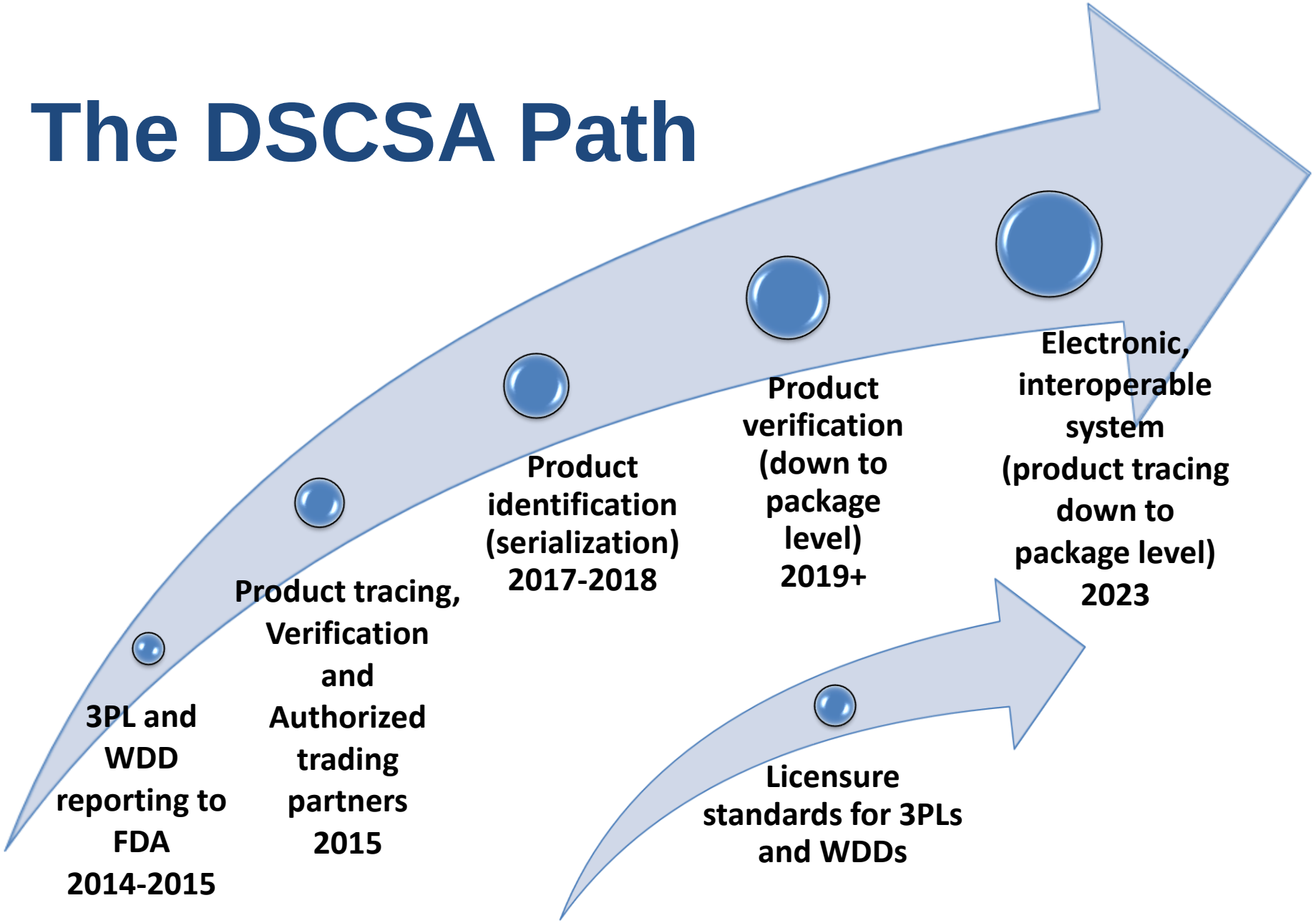
DSCSA goals

1. Implement an interoperable, electronic tracing of products at the package level by 2023 that will:

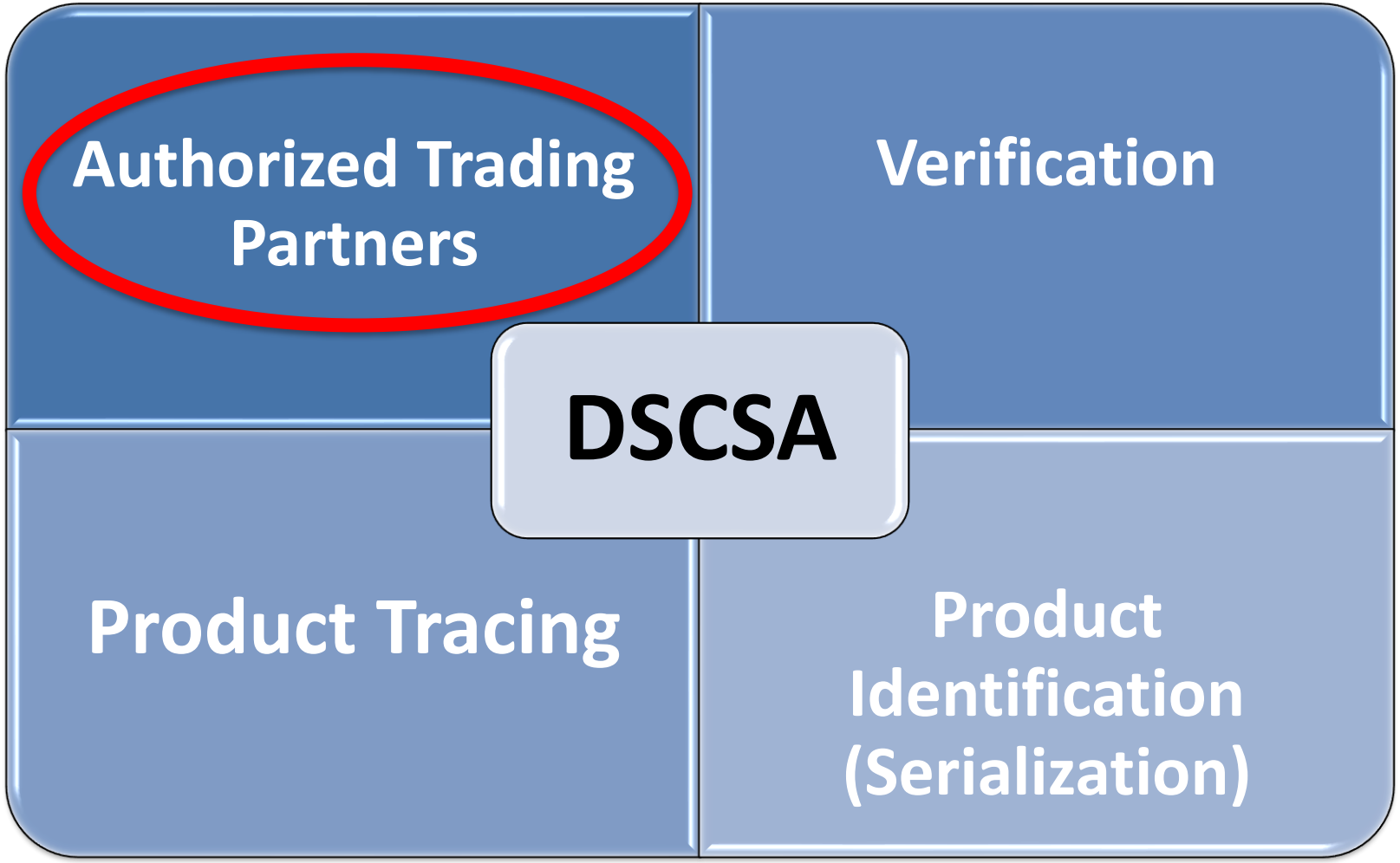
Enable secure tracing of product at the package level	Use product identifiers to verify product at the package level	Enable prompt response to suspect and illegitimate products when found	Improve efficiency of recalls

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

The DSCSA Path



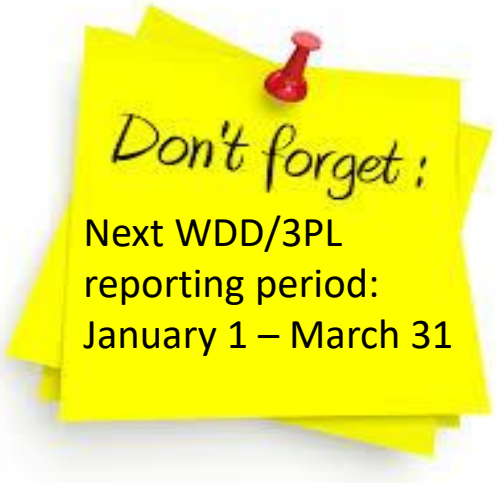
Key Requirements*

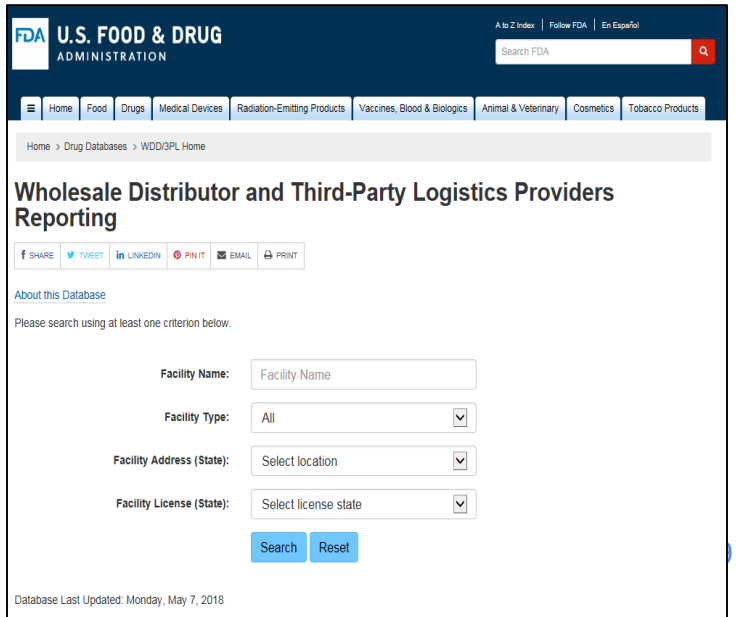


*The requirements under section 582 of the FD&C Act apply to manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies).

Where are we now?
Authorized trading partners

- Draft Guidance: Identifying trading partners
- Tools:
  - Drug Establishment Current Registration Site (DECRS) – Mfger/Repkger
  - Wholesale distributor/3PL database





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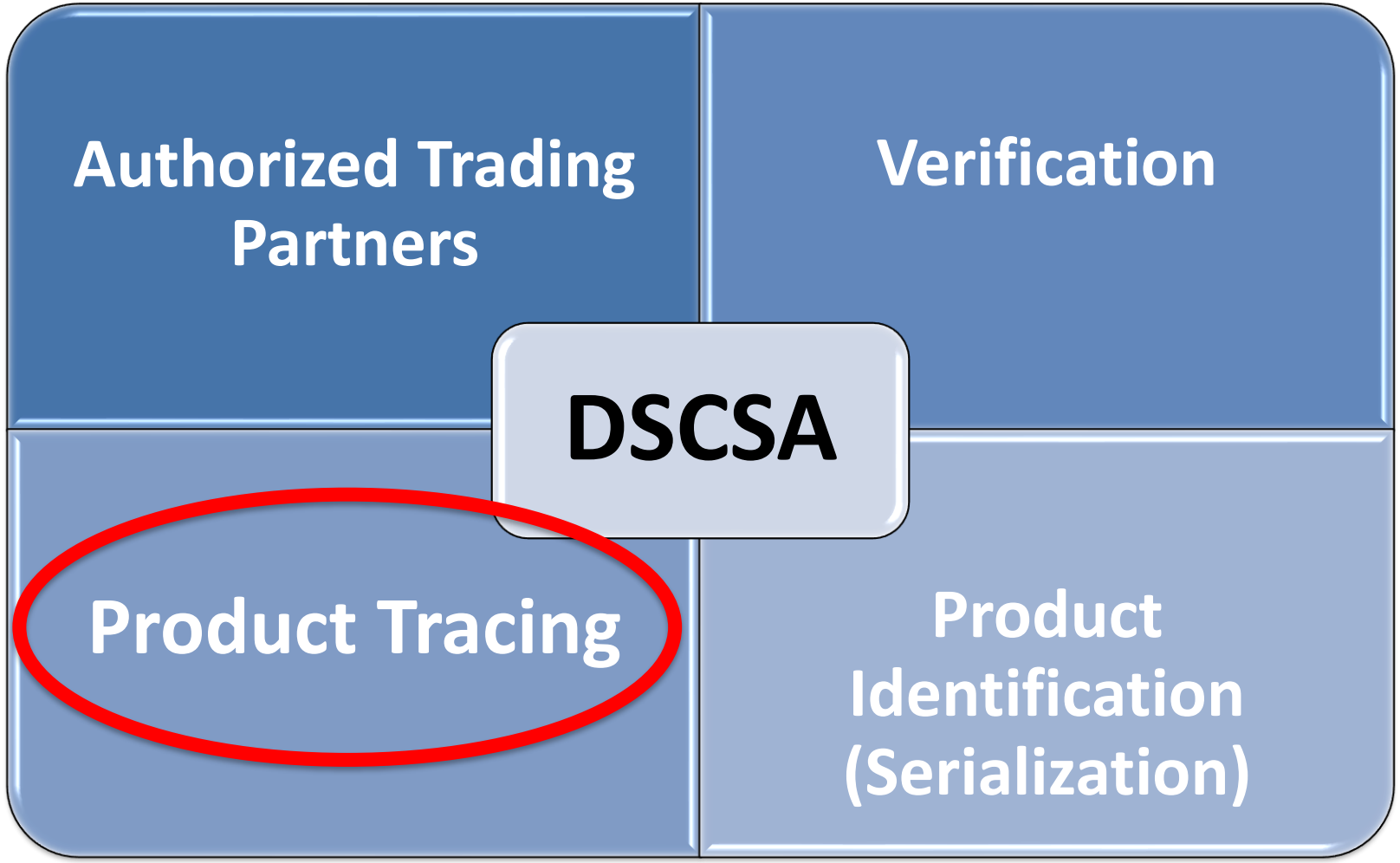

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Where are we now?
Product tracing

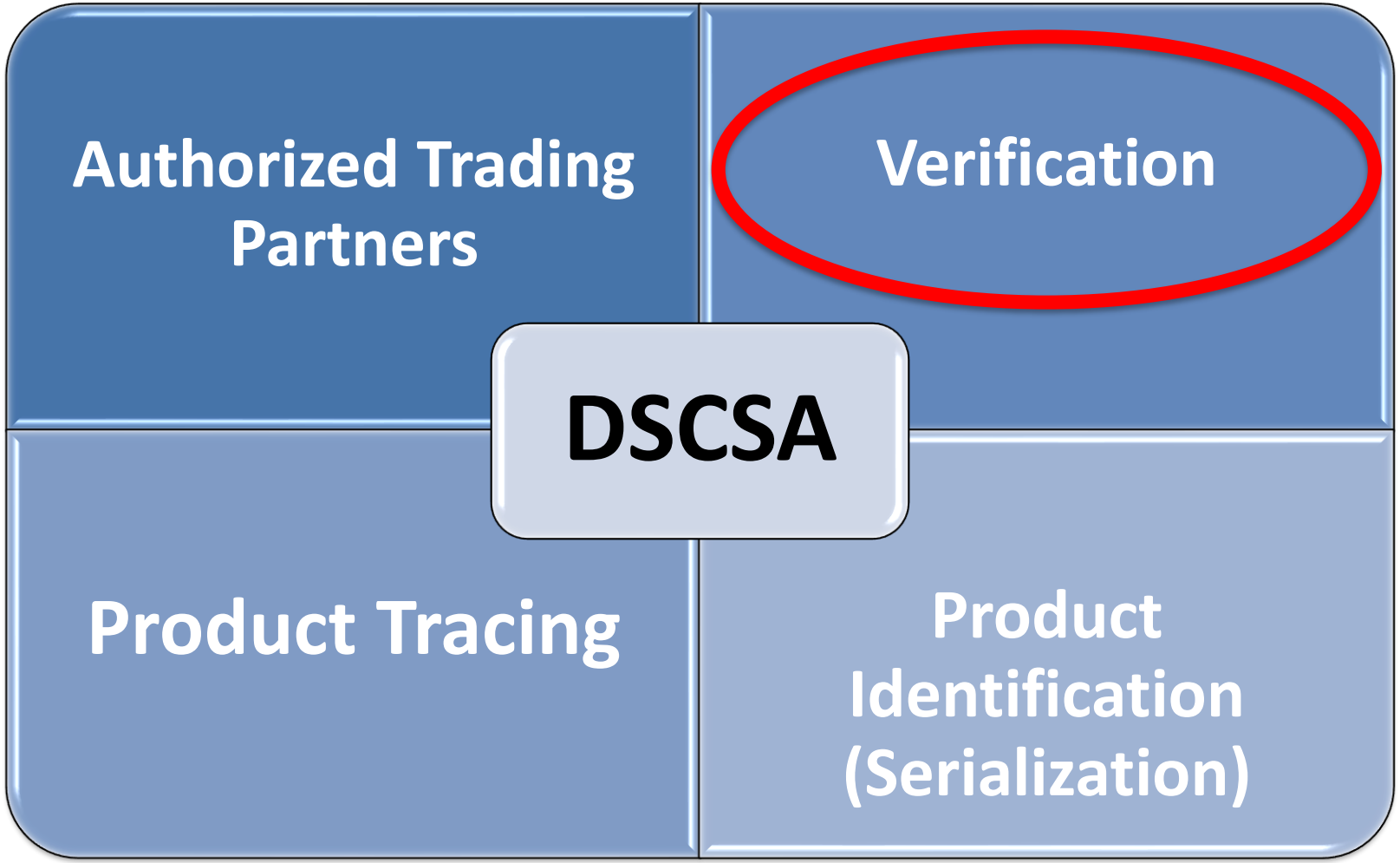
- Product tracing information
  - Comprehensive?
  - Accurate?
  - Electronic (from manufacturer)

- Draft Guidance: Standards
  - How to exchange product tracing information (2014)
  - Data and documentation (2018)

Draft Guidance: Standardization of data and documentation practices for product tracing (Mar. 2018)

- Recommends how to standardize the data contained in product tracing information (TI, TH, TS)
- Describes data elements that should be included in product tracing information, including situations where it is permitted by law for certain data to be omitted
- Dispenser to dispenser sales to fulfill a specific patient need
- Drop shipments to a dispenser
- Grandfathered product
- Use of third-party agreements

Key Requirements*



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Verification Requirements

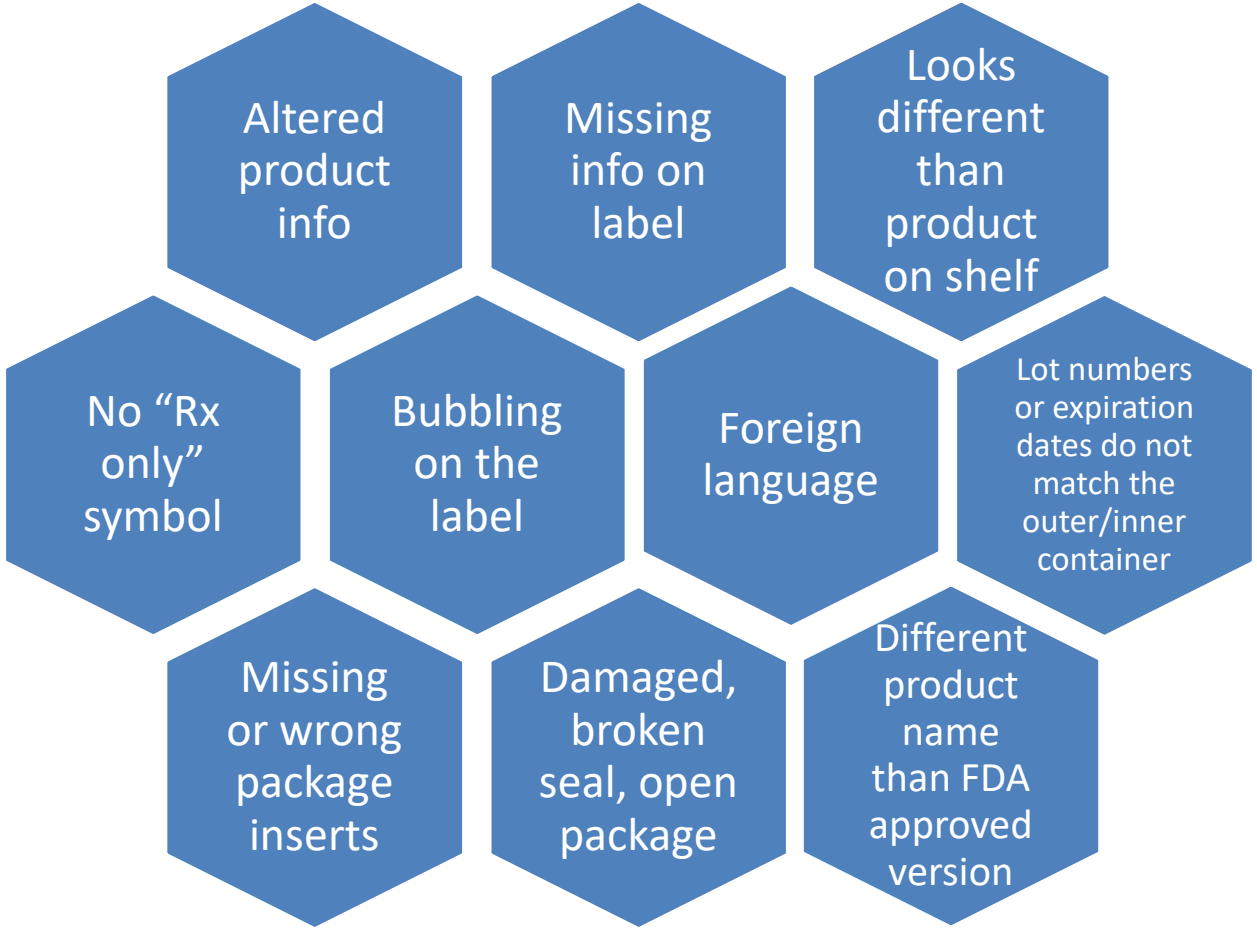
Quarantine and Investigate	Suspect prescription drugs to determine if illegitimate
Investigation	--Must include validating applicable transaction information and transaction history --Starting 2019/2020: Verify lot number and product identifier
Notify	If the product is illegitimate, notify FDA and certain immediate trading partners within 24 hours
Respond	If the product is illegitimate, work with manufacturer to take steps to prevent it from reaching patients
Store	Store records of investigation of suspect product and the disposition of illegitimate product for at least 6 years

Where are we now? Verification

- Guidances:
  - Identification of suspect product and notification (2016)
  - Definitions of suspect product and illegitimate product (2018)
  - Verification systems (2018) – *Docket open until 12/24/18*

- Notify FDA and trading partners
  - FDA: Form 3911

Identifying suspect product: Examples of what to look for…



Draft Guidance: Definitions of Suspect Product and Illegitimate Product for Verification Obligations (Mar. 2018)

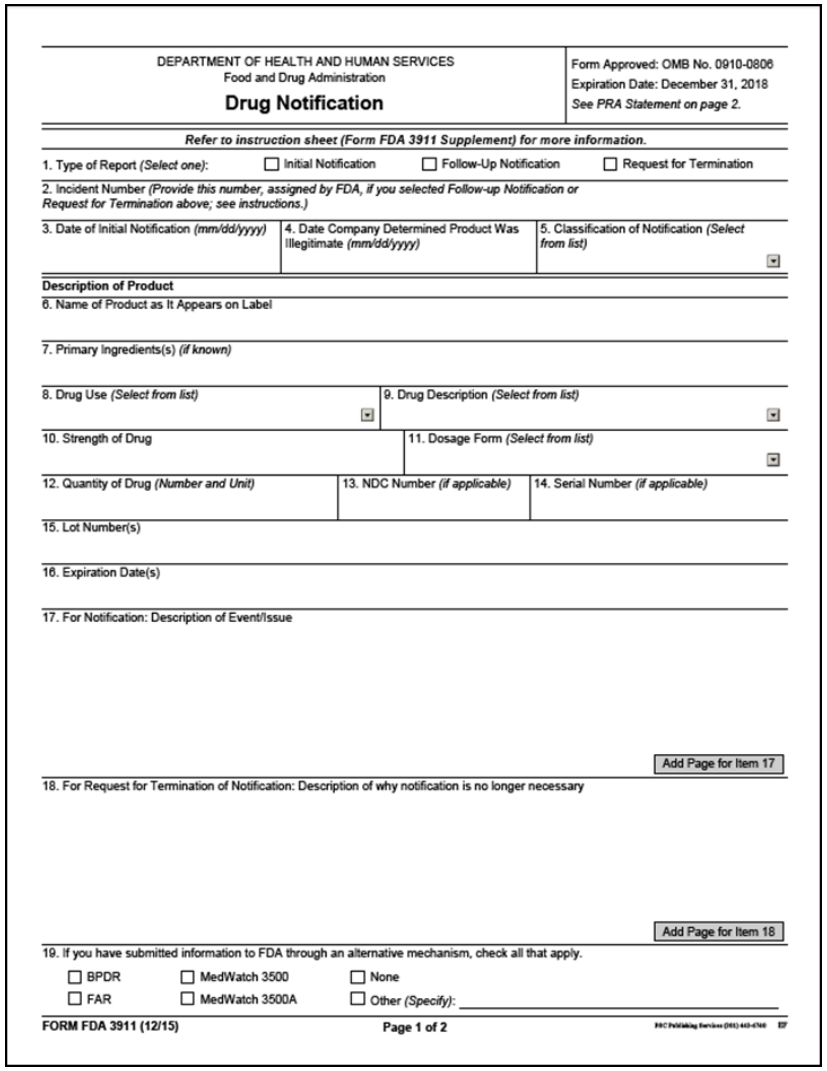
FDA's current thinking of terms used in the definitions of SUSPECT and ILLEGITIMATE product, for purposes of verification obligations, including notification

- Counterfeit
- Diverted
- Fraudulent Transaction
- Unfit for Distribution

Draft Guidance: Verification systems under DSCSA for certain prescription drugs (Oct. 2018)

- Recommendations for robust verification systems to:
  - quarantine and investigate suspect product
  - quarantine and disposition illegitimate product
- Recommendations for how and when to submit "cleared product notifications"
- Verification of saleable returns

Notify FDA if you have illegitimate product



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)*: _____

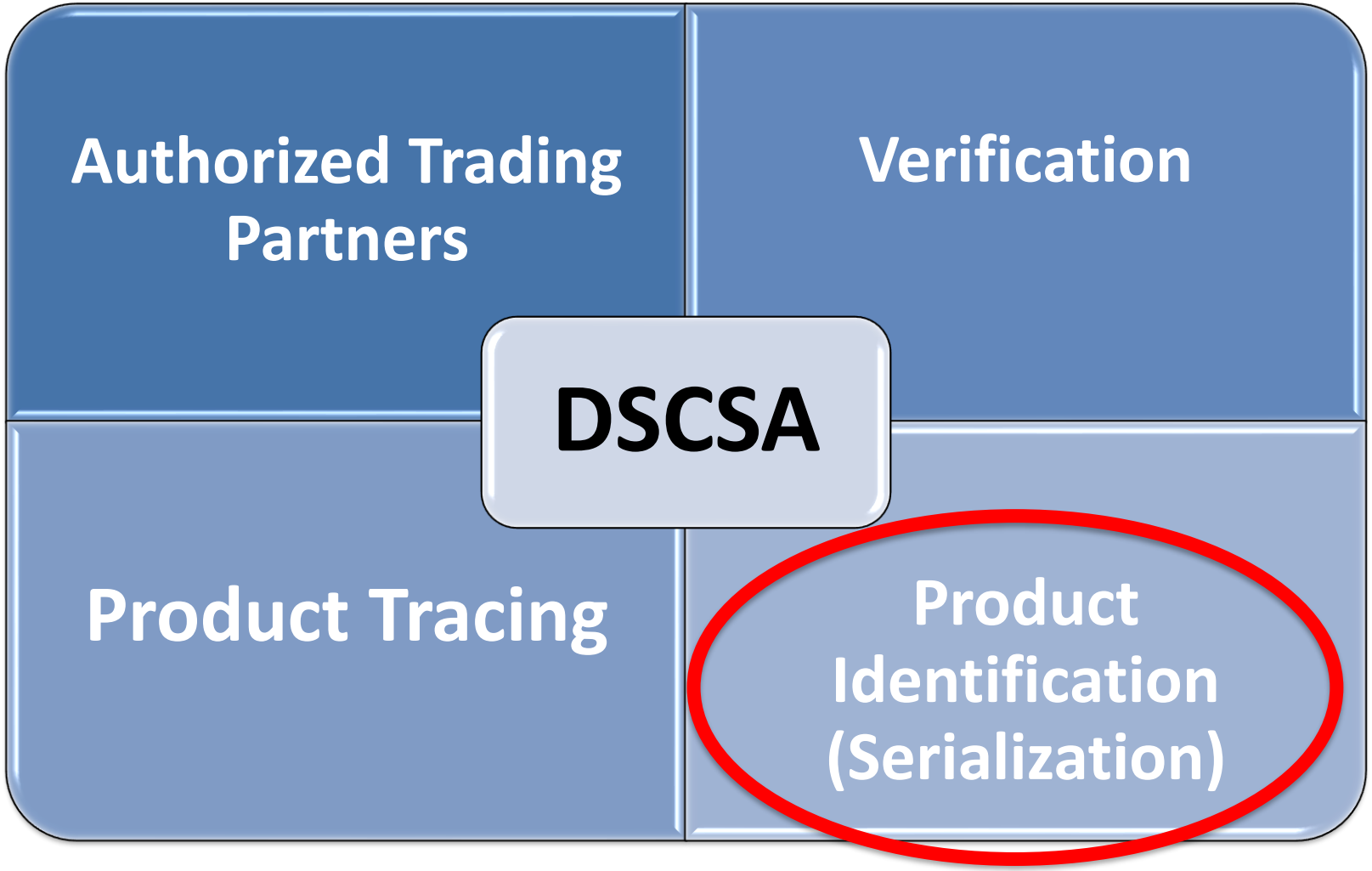
FORM FDA 3911 (12/15) **Page 1 of 2**

Notify FDA within 24 hours using Form FDA 3911

Notify other trading partners within 24 hours

Request notification termination using Form FDA 3911

Key Requirements*



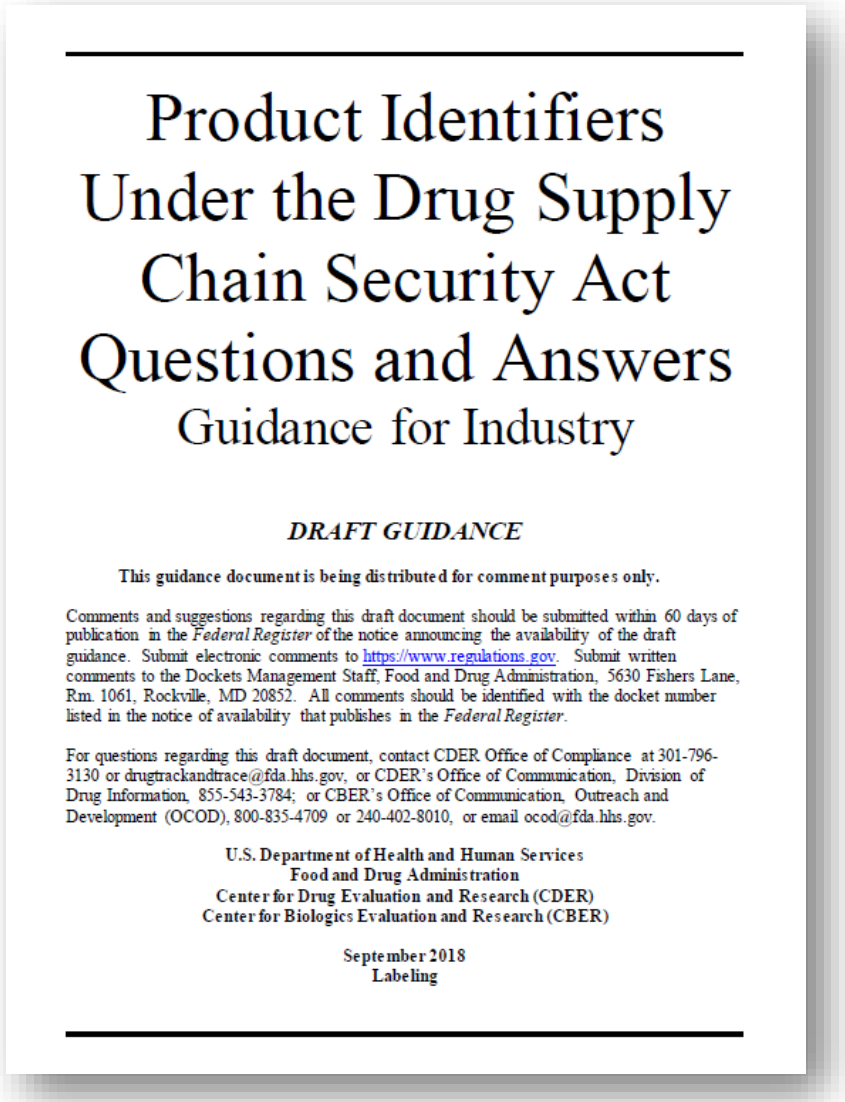
*The requirements under section 582 of the FD&C Act apply to manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies).

Where are we now?
Product identifiers (serialization)

- Product identifiers: **Implemented** as of **November 27, 2018**

- Guidances:
  - Qs and As *draft* (Sept. 2018)
  - Product identifier compliance (Sept. 2018)
  - Grandfathering (Sept. 2018)

Guidance: Product Identifier Requirements Q&A



Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers

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 https://www.regulations.gov. Submit written comments to the Dockets Management Staff, 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*.

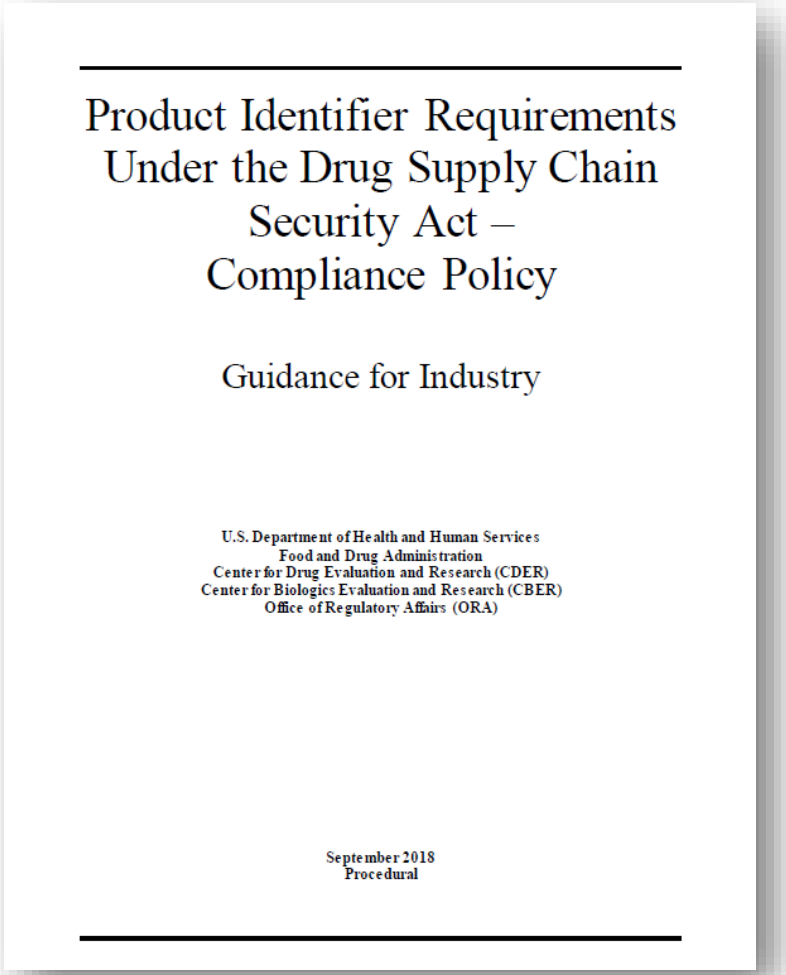
For questions regarding this draft document, contact CDER Office of Compliance at 301-796-3130 or drugtrackandtrace@fda.hhs.gov, or CDER's Office of Communication, Division of Drug Information, 855-543-3784; or CBER's Office of Communication, Outreach and Development (OCOD), 800-835-4709 or 240-402-8010, or email ocod@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)

September 2018
Labeling

- Agency Contacts
- Product Identifiers
- Submission of Label Changes under DSCSA
- Product Identifier Requirements of the DSCSA and the Linear Barcode Requirement under 21 CFR 201.25
- Examples of when the Product Identifier and/or the Linear Barcode are required

Final Guidances: Product Identifier Requirements



Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy

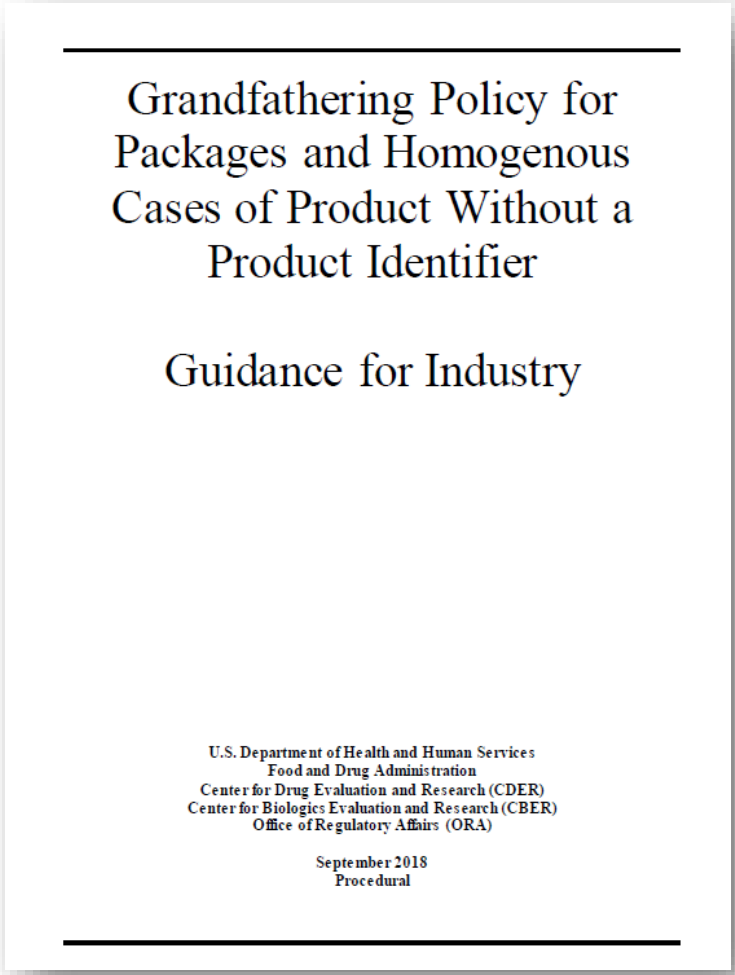
Guidance for Industry

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 2018
Procedural

Manufacturers have an additional year (until November 27, 2018)

If manufacturer's or repackager's product is packaged before November 27, 2018, considered grandfathered



Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier

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 2018
Procedural

Packages without product identifiers

Excluded Products	Not all prescription drugs are required to have a product identifier and are excluded.
Grandfathered	Some products will be in the supply chain before the product identifier requirement took effect.
Waiver or Exempt	Some products were granted a waiver or exemption from the product identifier requirement.

If you are unsure whether a product should have a product identifier, verify with the manufacturer or repackager.

Draft Guidance: Waivers, Exceptions, Exemptions (WEEs) (May 2018)

Sets forth a process for:

- Waiver request if undue economic hardship or emergency medical reasons
- Exception request if a product is in a container is too small or otherwise unable to accommodate
- Exemption for other products or transactions (FDA determination)

How to submit a WEE:

- Follow instructions in WEE Draft Guidance

Where are we now?
Proposed DSCSA Pilot Program

- FDA intends to initiate the DSCSA pilot project program soon.
- Announcement will be published in the Federal Register

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:

- Enable secure tracing at the package level
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products when found
- Improved efficiency of recalls

Public meeting series:
Enhanced Drug Distribution Security Under DSCSA

Goal: Gain stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA

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

FDA Leadership on DSCSA

"I want to be clear about our expectations regarding interoperability of the enhanced system. In 2023, the current requirement that trading partners share full transaction history for products will sunset. This does not mean that the historical information disappears. We'll have an interoperable, electronic system in place that promptly generates that historical information when needed."

"The FDA has an obligation to respond rapidly to breaches in the supply chain to protect patients from harmful drugs…Supply chain stakeholders also have an obligation to identify and prevent the distribution of illegitimate drugs."

"We want to create a system that flags illegitimate drugs in the supply chain."

– *Scott Gottlieb, M.D., Commissioner, FDA (Feb. 2018)*

Scott Gottlieb, M.D.
FDA Commissioner
@SGottliebFDA

Scott Gottlieb, M.D. @SGottliebFDA · 28 Nov 2017
#FDA issues guidance to implement policy when certain packages are grandfathered from provisions of the **Drug Supply Chain Security Act**

Scott Gottlieb, M.D. @SGottliebFDA · Sep 19
FDA is protecting patients from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The three guidances issued today will help industry enhance the security of the supply chain: go.usa.gov/xP2HU

Scott Gottlieb, M.D. @SGottliebFDA · Oct 10
....The U.S. drug supply system is among the safest in the world. But all of us -- #FDA included -- need to remain vigilant to protect patients from harmful or illegitimate drugs, such as counterfeits, by evolving and modernizing our practices.

Scott Gottlieb, M.D. @SGottliebFDA · Oct 10
THREAD: There has been attention to a major U.S. wholesaler's recent #FDA inspection. We expect all supply chain stakeholders to prevent, detect and respond to illegitimate products in the U.S. supply chain....

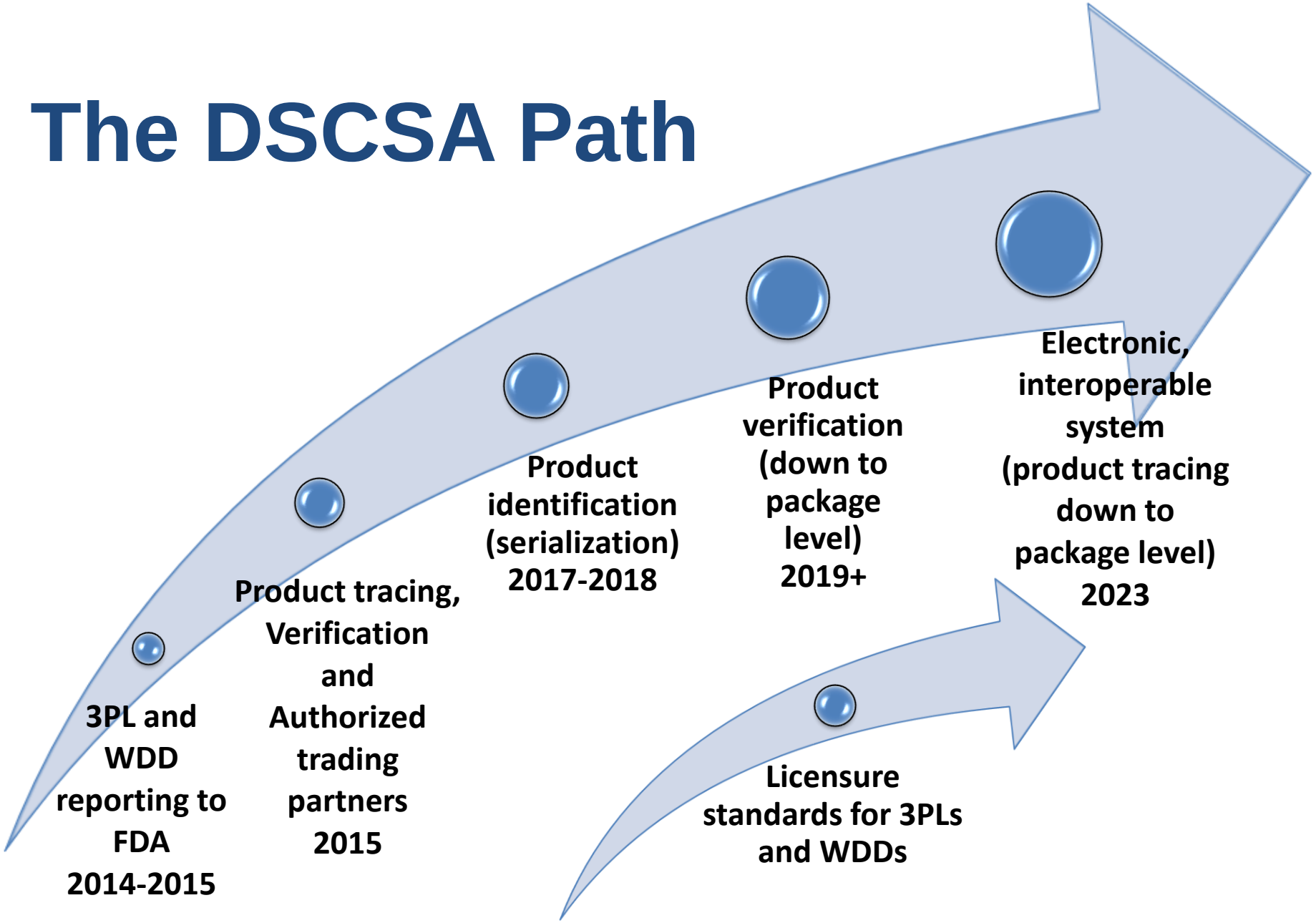
Scott Gottlieb, M.D. @SGottliebFDA · Oct 10
#FDA continues to take steps to improve the integrity of the U.S. drug supply chain and reminds manufacturers and repackagers of the 11.27.18 deadline to place unique identifiers on prescription drug packages.

Scott Gottlieb, M.D. @SGottliebFDA · Nov 27
Industry and #FDA have been working together for five years since the DSCSA was passed with the shared goal of further securing our nation's drug supply and today is a milestone as each package and case of products will have a unique identifier. go.usa.gov/xP6kD

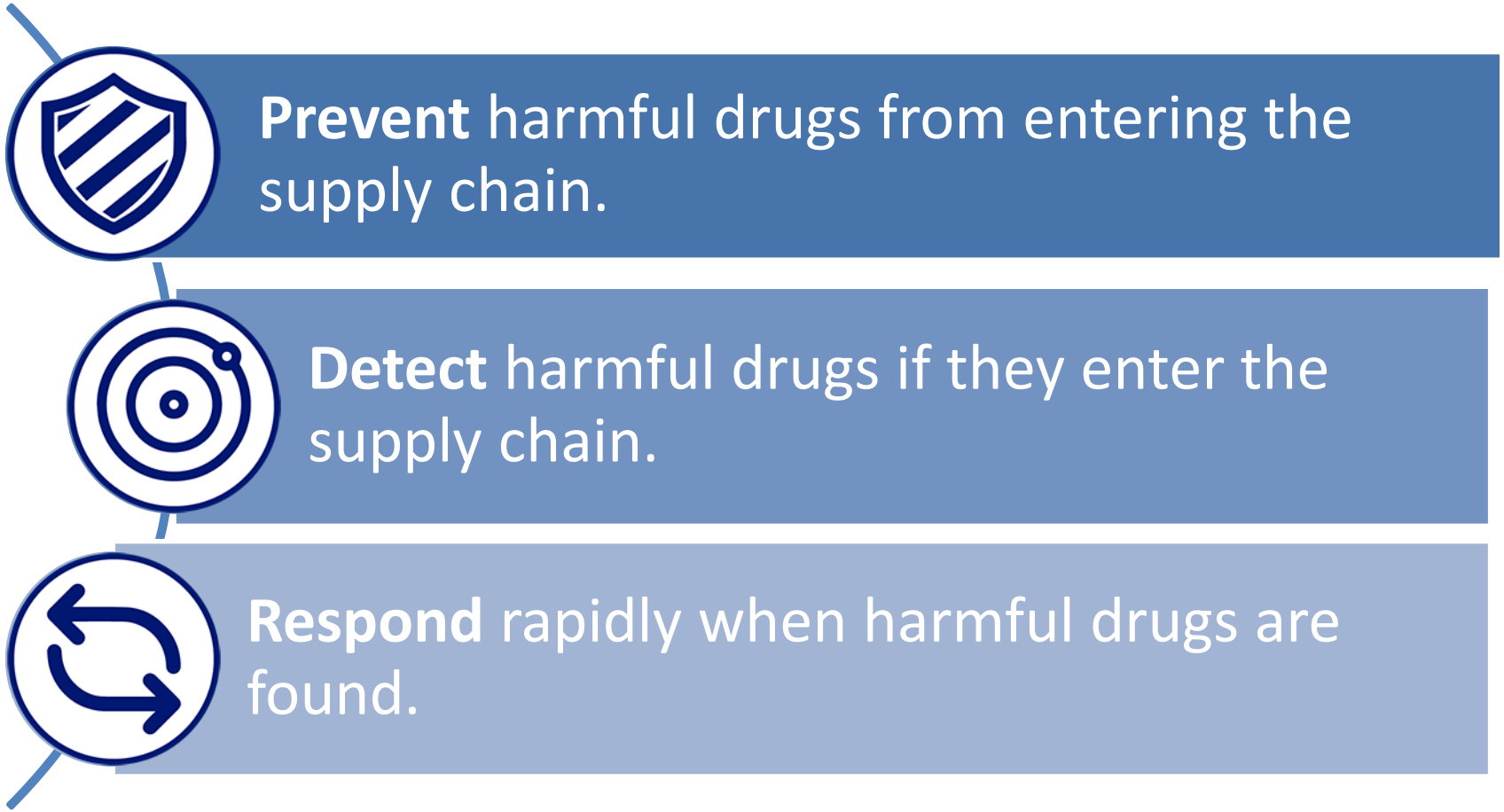
What's next? Program updates

- Pilot program
- Continued compliance and enforcement
- Wholesale distributor/3PL proposed rule & preemption
- Building infrastructure for licensing program

The DSCSA Path



Be vigilant and diligent!!



THANK YOU!!

Disclaimer

This presentation is intended only to provide a 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.

FDA documents or notices summarized in this presentation can be found on our Drug Supply Chain Security Act webpage.