Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

U.S. Food and Drug Administration

Public Meeting

October 14, 2016

Disclaimer

The content here is intended only to provide a overview for the purposes of the meeting. 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.

Purpose of today's public meeting

- 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.

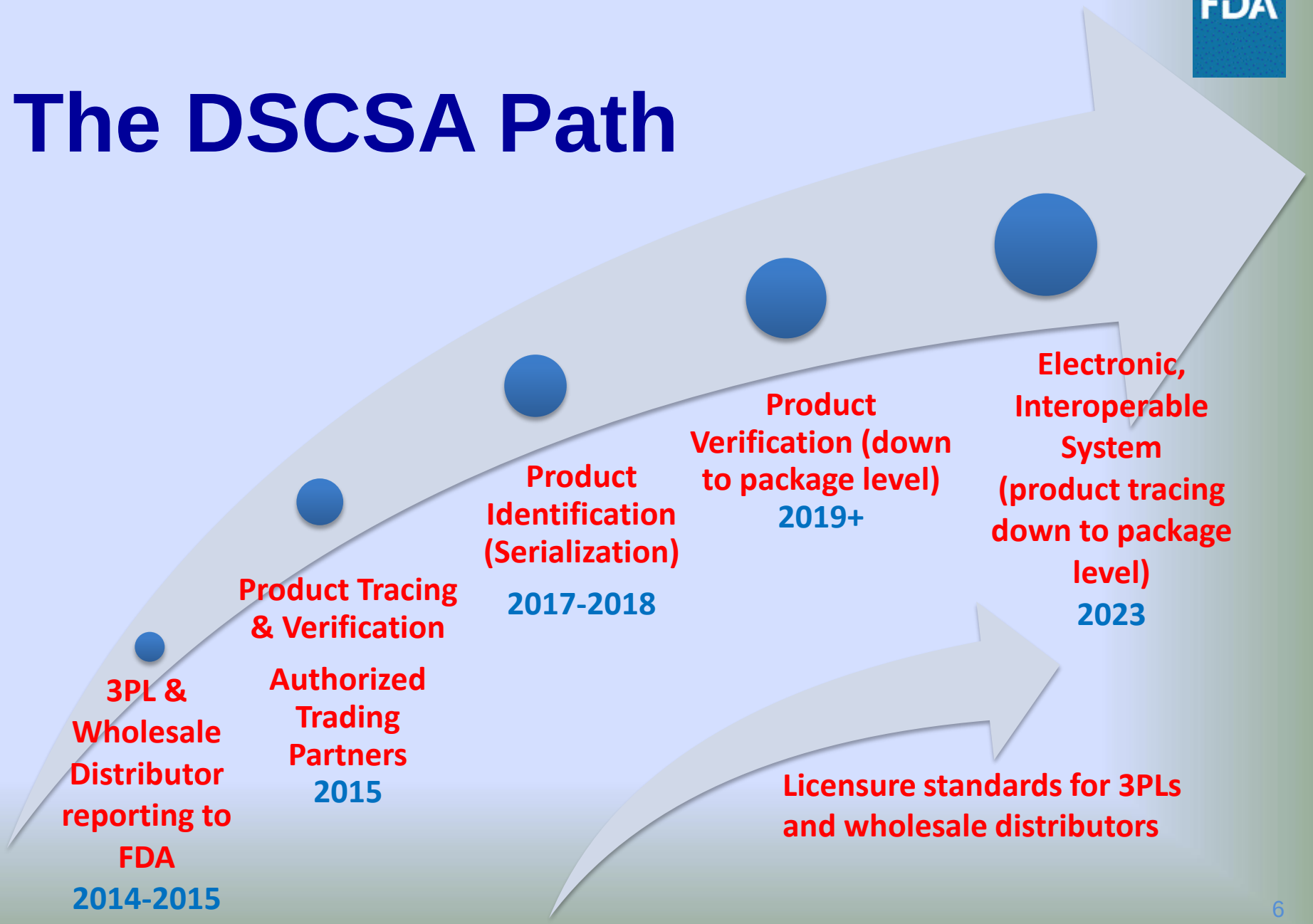
Meeting Logistics

- Purpose and DSCSA background (FDA)
- Stakeholders oral presentations (on-site sign-up)
- Followed by questions from FDA panel
- Audience members may also ask questions of the presenters.
- Open session – opportunity for additional comments from registered participants
- Today's meeting is being webcasted.
- Information captured will help inform FDA regarding industry's progress level with the DSCSA's product identification requirements.

Agenda

Friday, October 14, 2016		Speaker/Moderator
8:30 – 9:00 am	Registration	
9:00 – 9:15 am	Welcome Purpose Meeting Logistics	Dan Bellingham
9:15 – 9:30 am	DSCSA Background	Ilisa Bernstein
9:30 – 10:30 am	Stakeholder Presentations	Dan Bellingham
10:30 – 10:45 am	Break	
10:45 – 11:45 am	Stakeholder Presentations	
11:45 – 1:00 pm	Lunch	
1:00 – 2:00 pm	Stakeholder Presentations	
2:00 – 2:15 pm*	Break	
2:15 – 2:45 pm*	Stakeholder Presentations	
2:45 – 3:00 pm*	Open Session	
3:00 – 3:15 pm*	Closing Remarks	Connie Jung
	Adjourn	
	** times may change based on the number of oral presentations by stakeholders and the open session*	

The DSCSA Path



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)*
  - 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—

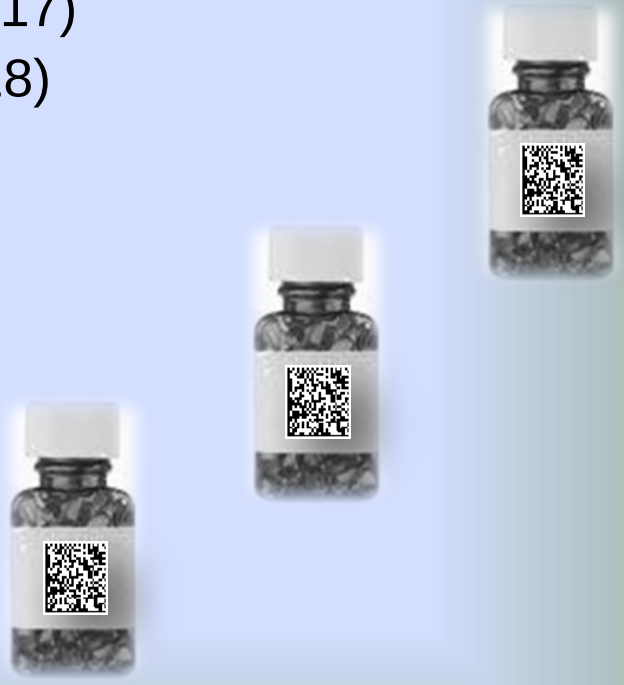
- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- 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.

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 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

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

Presentations

1. Anita Ducca & Brian Waldman (Healthcare Distribution Alliance)
2. Heather Zenk (AmerisourceBergen)
3. Scott Mooney (McKesson)
4. Mark Hendrickson (Generic Pharmaceutical Association)
5. Eric Marshall (Pharmaceutical Distribution Security Alliance)
6. Riya Cao (LSPediA)
7. Susanne Somerville & Eric Garvin (The LinkLab)
8. Mike Rose (Johnson & Johnson)
9. JP Allard (Optel Vision)

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

How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2016-N-2673.
- Public meeting docket will close on Nov. 14, 2016.
- Stakeholder input essential and valued!

(Early submissions appreciated)