US Drug Supply Chain Security Act
“Will Industry Be Ready?”

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Disclaimer:

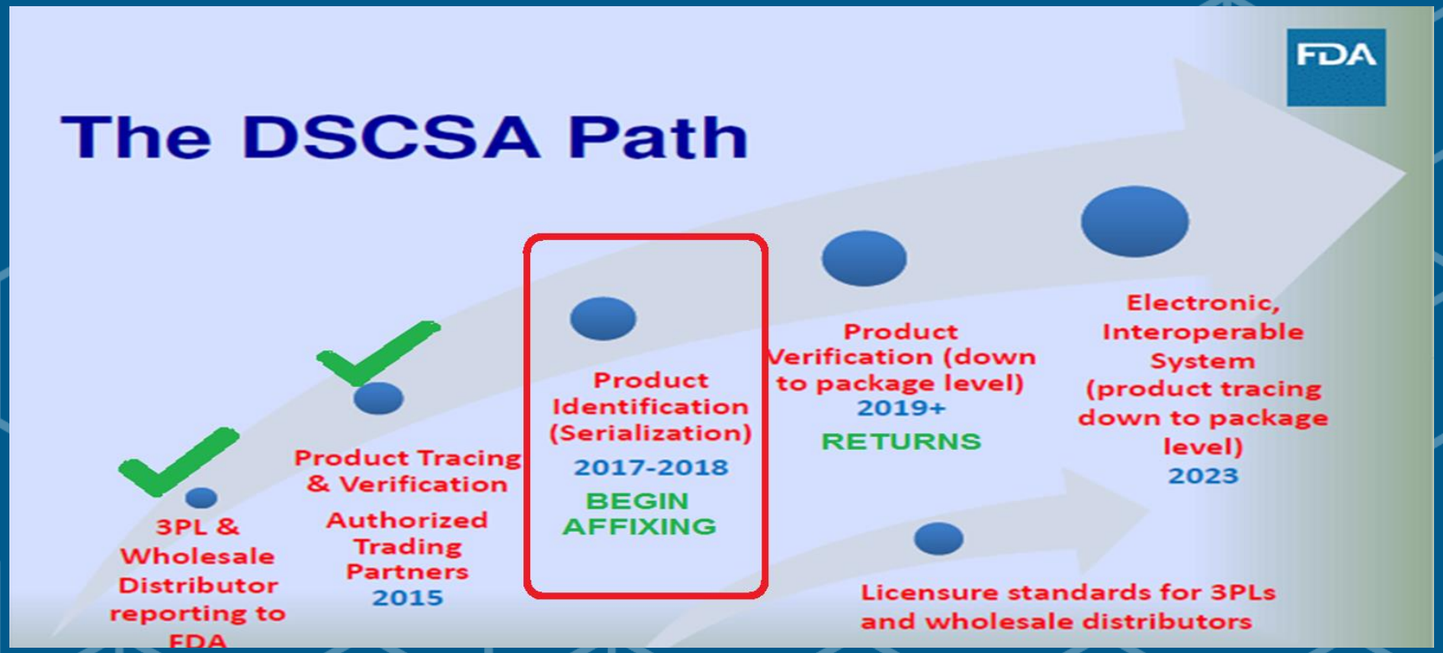
I am not a representative of the US FDA. The content provided in this presentation is intended to be informational only and not legal advise. All parties should verify with their own regulatory resources their requirements under the Drug Supply Chain Security Act.

Slide Content from FDA Presentation at HDA Traceabilty Conference Oct, 2018 with green added by McKesson

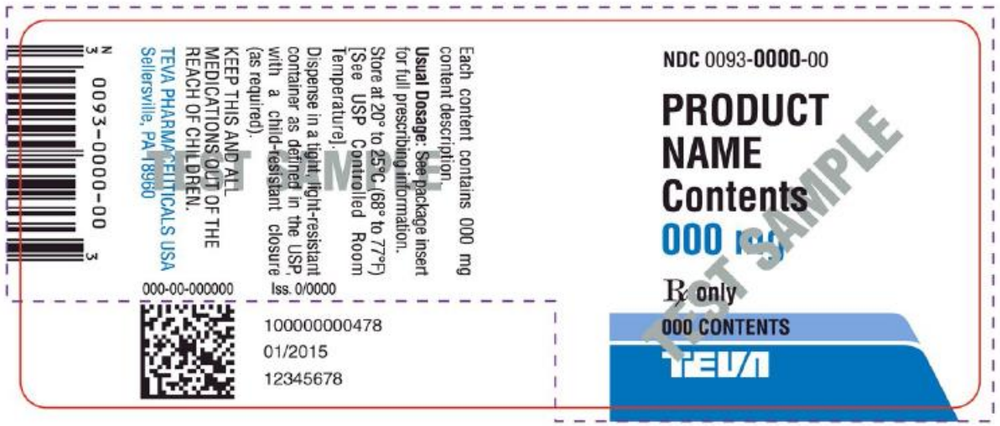
Initial DSCSA began in 2015

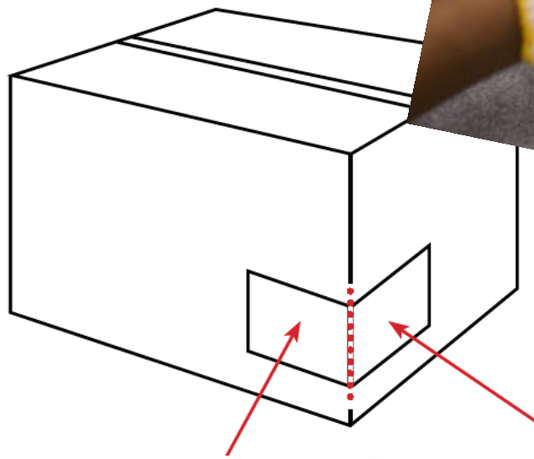
- Manufacturers and Distributors began passing basic DSCSA data
  - Could be paper or electronic. Manufacturers are now electronic only after Nov 2017
  - Illegal to receive DSCSA product without first having DSCSA data from seller
- <u>These initial basic DSCSA requirements remain until 2023</u>
- Lot numbers are exempt for direct purchased product in the DSCSA data and a Direct Purchase Statement is required instead
- Trading partners must each have a policy for Suspect and Illegitimate Product Investigations

2017/2018 Requirements Underway: Product Marking



DSCSA 2018 Labeling Requirements





2017/2018 is ALL about labeling product and NOT passing serialized data

Current State of 2D Bar Coding in Supply Chain

- McKesson joined GS1 US, ABC and Cardinal in 2018 Bar Code Survey
- Scanned 26,000+ products to capture and analyze linear and 2D bar codes on current products
  - Generated a public report with suggestions for best practice
  - Provided reports to manufacturers on their products compliance
  - 21% of current products in commerce have the 2D bar code with the four elements encoded: GTIN(NDC), Serial, Lot, Expiry

Results of packages and cases

At AmerisourceBergen

20.4%

(1,025 packages)[1]

had a readable barcode with all four DSCSA-required data elements (compared to 7.2% in 2017).

At McKesson Pharmaceutical

20.8%

(3,365 packages)[2]

had a readable barcode with all four DSCSA-required data elements (compared to 6.5% in 2017).[3]

At Cardinal Health

15.1%

of homogeneous cases had 2D (GS1 DataMatrix) readable barcodes with all four DSCSA-required data elements.

[1]AmerisourceBergen assessed specialty medications. [2]McKesson assessed prescription pharmaceuticals. [3]Results from the GS1 US-scanned sample at McKesson were similar at 19.8%. Source: GS1 US, "2018 Update: Implementation of DSCSA Serialization Requirements" report

- Scanned packages and cases from the forward pick locations in the wholesaler DC's
- Average expiration dating was 2.3 years
- Many of these products were serialized before 2018

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Learn More

https://www.gs1us.org/industries/healthcare/standards-in-use/dscsa/datamatrix-barcode

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Product Labeling Guidances Issued

- Manufacturers received Enforcement Discretion allowing them to delay until Nov 2018 to begin affixing new 2D bar codes
- Manufacturers and Repackagers received Grandfathering Guidance allowing them to continue to sell unserialized product until it expires if it was packaged before Nov 2018
- FDA issued guidance for human readable data on September, 2018
- FDA reinforced that linear bar code requirements remain and were unaffected by the DSCSA

FDA Guidance Q&As on product identification

4. How should the human-readable portion of the product identifier required by the DSCSA be formatted to appear on the drug package label?

To aid healthcare practitioners that may use product information, such as checking the expiration date or recording the NDC and lot number into a patient record, in the human-readable portion of the product identifier, FDA recommends that the human-readable product identifier appear in the following format:[24]

NDC: [insert product's NDC]
SERIAL: [insert product's serial number]
LOT: [insert product's lot number]
EXP: [insert product's expiration date]

FDA recommends that the human-readable expiration date include year, month, and non-zero day

YYYY-MM-DD only numerical
YYYY-MMM-DD alphabetical

If there are space limitations on the drug package,

YYYY-MM only numerical
YYYY-MMM alphabetical

FDA recommends using a hyphen or a space

FDA Guidance Q&As on product identification

5. Can the GS1 Global Trade Identification Number (GTIN) be used in place of the NDC to comply with the requirements for a human-readable NDC as part of the product identifier?

No. The product identifier on the product label must contain the NDC.[25] The NDC is currently a 10 or 11-digit number, in its FDA-assigned 3-segment format, that identifies the labeler, product, and trade package size.[26]

While industry's practice is to use a GTIN that may incorporate the digits of the NDC, the GTIN typically contains additional digits and is not in the 3-segment format by which the NDC is defined in FDA regulations.[27] Moreover, FDA is concerned that use of the GTIN alone in the human-readable portion of the product identifier could lead to improper identification of the NDC and drug product. If the NDC is on the label in its FDA-assigned 3-segmant format, a company may also voluntarily affix or imprint the associated GTIN on the label.

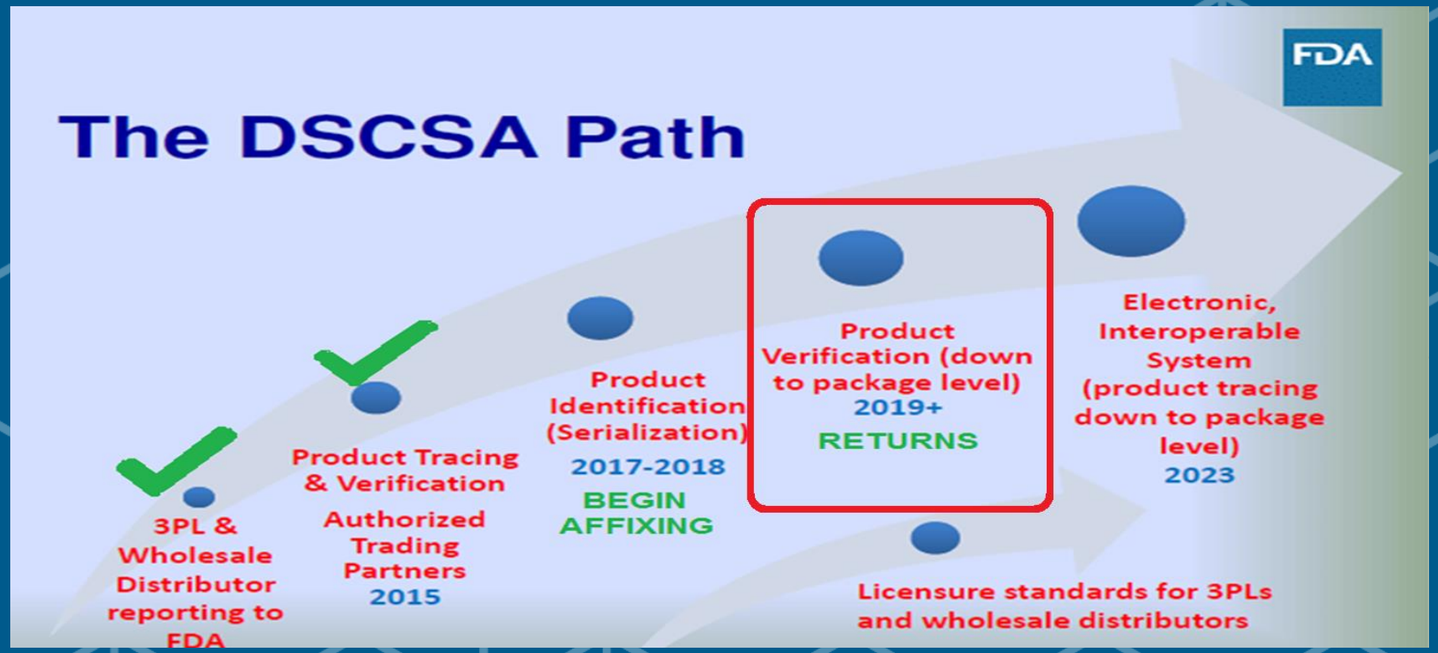
Product Identifier Deadline Nov 27, 2018

"there will be no more extensions" for product identifiers.

Dr. Ilisa Bernstein of FDA's CDER section commented on October 18, 2018 at the HDA Traceability Conference in Washington, DC.

However, manufacturers and repackagers may still apply for consideration of a waiver, exception or exemption to the FDA. It is unknown how many applications the FDA may have received or plan to approve.

2019 Requirements under Development: Returns Verification



NEW Returns Requirements

Distr

1) Distributors must associate the original Transaction Information, Transaction History and Transactional Statement with a saleable return.

Both Mfgr & Distr

2) Verify that the product identifier affixed to the product corresponds with the data the manufacturer assigned.
   - Manufacturers can send serialized data for their shipments to their trading partners to be used for verification of future saleable returns [EPCIS]

--- OR---

   - Manufacturers can make serial data available for query using a Verification Router Service requesting data for the distributors

Annual saleable returns in US estimated at 60 million pieces across the industry

McKesson saleable returns approximately 19 Million per year

GS1 Lightweight Verification Messaging Standard Positioning within the GS1 Architecture

- **New addition** to the 'Share' layer and operates at a higher level than EPCIS.
  - Request/Response message
- **First** GS1 ‘Share’ standard to leverage the new **GS1 Digital Link (Web URI)** standard for the request syntax.
- **First** GS1 standard to include **JSON** as a message response syntax;
- Can be viewed as a minimal kind of Checking Service:
  - **Input**: a serialized Product Identifier (GTIN) and other parameters
  - **Triggers** an authentication check of the Product Identifier
  - **Output**: Actionable information that enables a decision about how to handle the product
    - Whether product is viable for forward distribution OR should be rejected OR quarantined

GS1 Lightweight Verification Messaging Standard Relationship to EPCIS

- Verification Messaging Standard is independent of EPCIS and does not require the use of EPCIS.
  - Users are encouraged to implement EPCIS to capture their supply chain events and to leverage the EPCIS query interface to retrieve the data required to respond to a request for product verification.
- Verification Messaging Standard requires lightweight or convenient interface to perform a simple verification check of Product Identifiers at batch or serial level
  - While EPCIS event data can record the commissioning, or decommissioning of products, as well as current disposition (such as 'recalled') and instance/lot master data (such as 'expiry date'), **EPCIS does NOT function as a minimal kind of checking service** of product identifiers at batch or serial level

GS1 Lightweight Verification Messaging Standard Milestones

Milestone deliverables	
Milestones	**Deliver date/status**
Requirements complete	12 July
Requirements Community Review	27 July
Requirements eBallot approved	16 August
Application Standard complete	31 October
Application Standard Community Review	16 November
Application Standard IP Review	30 November
Complete eBallot	30 November
Ratification & publication	15 December

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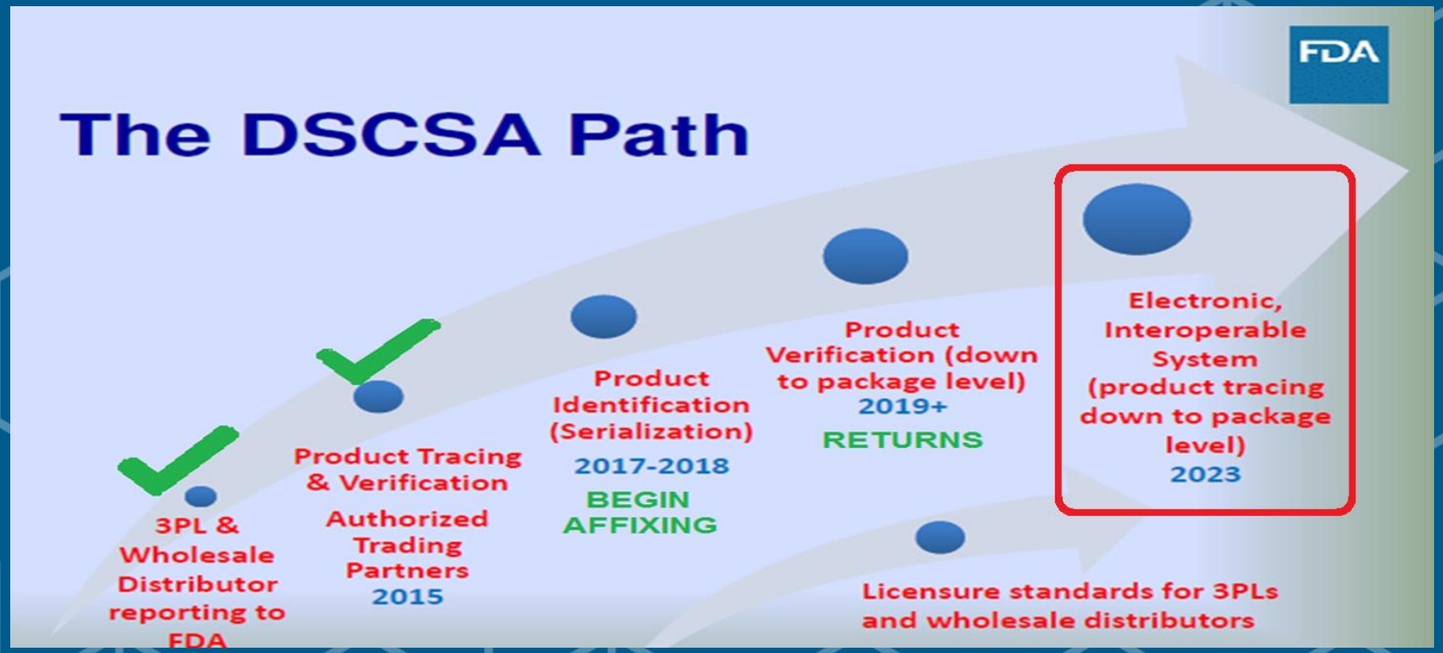
2023 Requirements: Exchanging Serialized DSCSA Data



Serialized DSCSA Data Exchange

- Transaction History sunsets in DSCSA transaction data
  - Replaced with ability to “facilitate the gathering” of transactions
- Serial number, Lot Number and Expiry become mandatory as a part of the DSCSA transaction data
- Method of exchanging DSCSA data with ASNs will change to EPCIS which is better suited for serial numbers
- What is meant by “Interoperable” in the DSCSA is under significant discussion across industry

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Questions?