Enhanced Drug Distribution Security in 2023 Under the Drug Supply Chain Security Act (DSCSA)

FDA Public Meeting
November 16, 2021

Opening Remarks

Donald D. Ashley, J.D.
Director
FDA/CDER/Office of Compliance

Purpose of the Meeting

To provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to provide input on the implementation of the enhanced drug distribution security provisions of the DSCSA that go into effect in 2023.

Objectives of the Meeting

- Learn about how implementation of the 2023 enhanced system requirements is progressing for organizations across the pharmaceutical distribution supply chain
- Learn about what challenges organizations are facing with implementation of the 2023 requirements
- Identify how helpful the proposed recommendations are in FDA's guidance on enhanced drug distribution security at the package level to achieve compliance with the 2023 requirements

Meeting Logistics

- All meeting attendees are in listen-only mode only(except speakers & moderators).
  - Today's format will only allow for the FDA panel to ask questions to speakers
  - The chat should only be used for technical support
- **For attendees**
  Use your computer audio to listen; no separate dial-in is needed.
- A recording of the meeting and slides will be available on the webpage after the meeting

Meeting Logistics

- Selection to speak today should not be interpreted as FDA's position on an entity's compliance with regulatory requirements or an endorsement of a particular technology, system, or approach.
- Speakers should avoid presenting any promotional material related to your organization.
- **Confirmed speakers** will be presenting during their allotted time on the agenda.
- **Open Comment Session (3:00 - 3:45 pm)**
  - Additional speakers may present oral remarks for a maximum of 5 minutes each.
  - To request a slot, email your request with your name and organization to: CDERODSIRPublicMeetings@fda.hhs.gov no later than 12:40 pm.
  - Requests received after 12:40 pm will not be accommodated, and comments can be submitted to the public docket.
  - We will do our best to accommodate up to 8 speakers during this session.

Submit Comments to the Public Docket

- Submit either electronic or written comments on this public meeting [Docket No. FDA-2021-N-1004] by January 18, 2022.
- Follow instructions in the Federal Register Notice:

  https://www.federalregister.gov/documents/2021/10/15/2021-22474/enhanced-drug-distribution-security-at-the-package-level-under-the-drug-supply-chain-security-act

U.S. Food and Drug Administration
Public Meeting: Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act (DSCSA)

Docket No. FDA-2021-N-1004

Tuesday, November 16, 2021: 9:00 am – 4:00 pm EST

AGENDA

9:00 am	Welcome	Daniel Bellingham *Policy Analyst, Office of Drug Security, Integrity and Response (ODSIR), CDER/OC/FDA*
9:00 am – 9:05 am	Opening Remarks	Donald D. Ashley, J.D. *Director, Office of Compliance, CDER/FDA*
9:05 am – 9:10 am	Goals of the Public Meeting and Logistics	Daniel Bellingham
9:10 am – 9:35 am	Overview of Enhanced Drug Distribution Security	Abha Kundi, J.D., M.P.H. *Regulatory Counsel, ODSIR, CDER/OC/FDA*
	Stakeholder Presentations	
9:40 am -9:50 am	Pharmaceutical Distribution Security Alliance (PDSA)	Mark Hendrickson
9:50 am – 10:00 am	Partnership for DSCSA Governance, Inc. (PDG)	Eric Marshall
10:00 am – 10:10 am	Pharmaceutical Research and Manufacturers of America (PhRMA)	Ryan Kaat

10:10 am – 10:20 am	Novartis	Dave Mason
10:20 am – 10:30 am	FDA Questions to Speakers	
10:30 am -10:50 am	*Break*	
10:50 am – 11:00 am	Healthcare Distribution Alliance (HDA)	Anita Ducca
11:00 am – 11:10 am	Cardinal Health	Maryann Nelson
11:10 am – 11:20 am	McKesson	Scott Mooney
11:20 am – 11:30 am	Smith Drug Company	Brad Pine
11:30 am – 11:40 am	FDA Questions to Speakers	
11:40 am – 12:40 pm	*Break*	
12:40 pm – 12:50 pm	American Pharmacists Association (APhA)	Ilisa Bernstein
12:50 pm – 1:00 pm	Walgreens	Michele Davidson
1:00 pm – 1:10 pm	FDA Questions to Speakers	
1:10 pm – 1:50 pm	*Break*	
1:50 pm – 2:00 pm	National Association of Boards of Pharmacy (NABP)	Josh Bolin
2:00 pm – 2:10 pm	Softgroup	Iordan Dunkov
2:10 pm – 2:20 pm	LSPEDIA	Riya Cao
2:20 pm- 2:30 pm	FDA Questions to Speakers	
2:30 pm – 3:00 pm	*Break*	
3:00 pm – 3:45 pm	*Open Comments Session*	Moderator: Daniel Bellingham
3:45 pm – 3:55 pm	FDA Questions to Speakers	
3:55 pm – 4:00 pm	Closing Remarks	Leigh Verbois, PhD

The Drug Supply Chain Security Act DSCSA

- Enacted November 27, 2013
- Outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Improves detection and removal of potentially dangerous drugs from the drug supply chain

DSCSA Goals

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

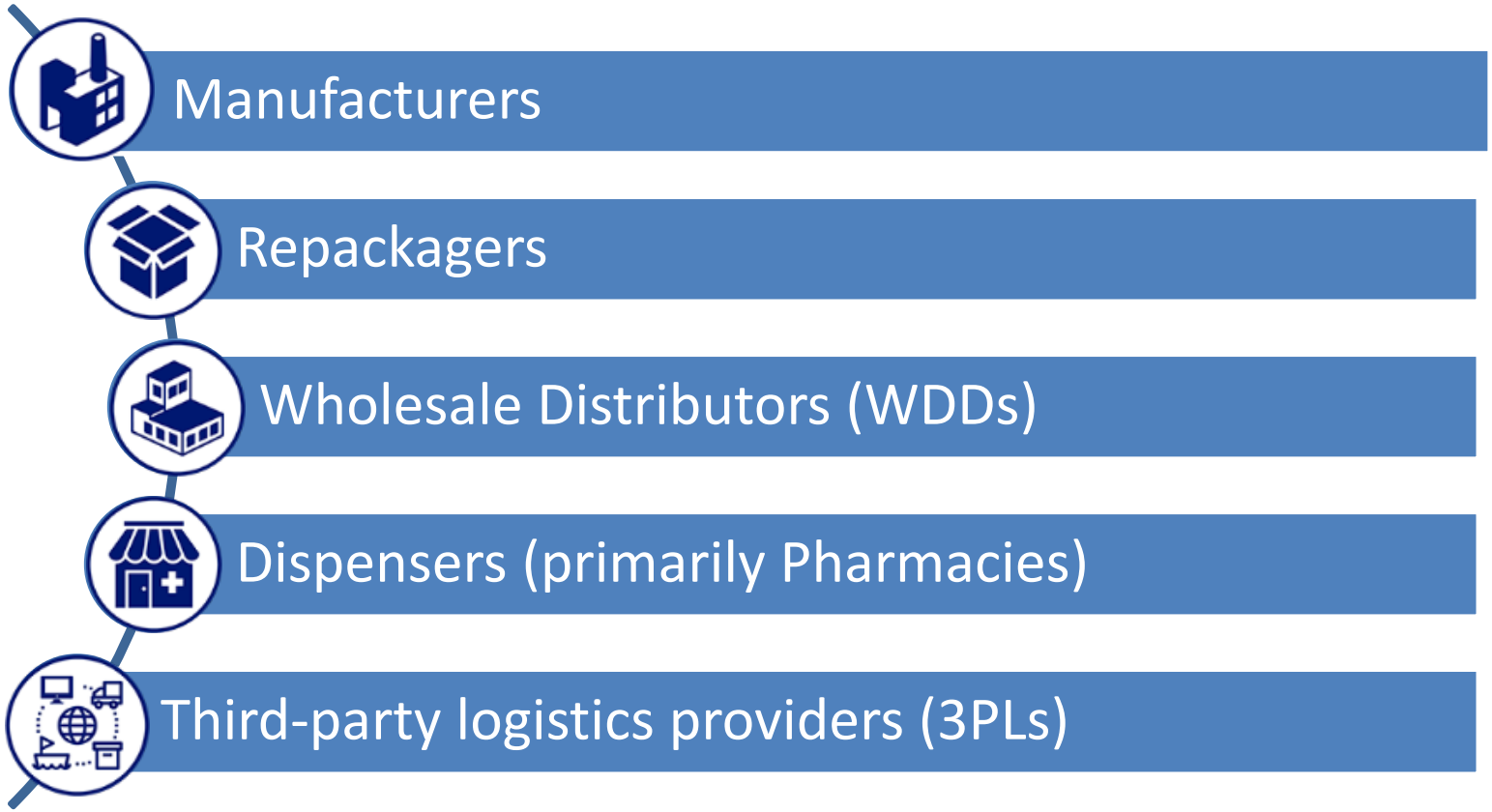
- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect and illegitimate products when found
- Improve efficiency of recalls

2. Establish national standards for licensure for wholesale distributors and third-party logistics providers (3PLs)

DSCSA Key Requirements

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

Trading Partners under DSCSA



Products

- 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

Refer to the definition for "product" in section 581(13) of the FD&C Act for specific information regarding exceptions.

Transactions

- Involve transfers of product where a *change of ownership* occurs
- Excludes:
  - 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 the definition for "transaction" in section 581(24) of the FD&C Act for specific information regarding exclusions.

Product Tracing Information

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

Investigate and properly handle suspect and illegitimate products

Suspect Product: ***reason to believe*** that product potentially is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Illegitimate Product: ***credible evidence*** shows that the product is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Notify FDA of Illegitmate Product within 24 hours (Form FDA 3911) and other trading partners within 24 hours

Product Identifier (Serialization)

Manufacturers/Repackagers (November 2018)

- Encode product identifiers on prescription drug packages
- Determine smallest individual saleable unit
- Verification requirements changes once products are serialized with product identifier

NDC: XXXX-XXXX-XX
SERIAL: XXXXXXXX
LOT: XXXXXXX
EXP: YYYY-MM-DD

Product Identifier

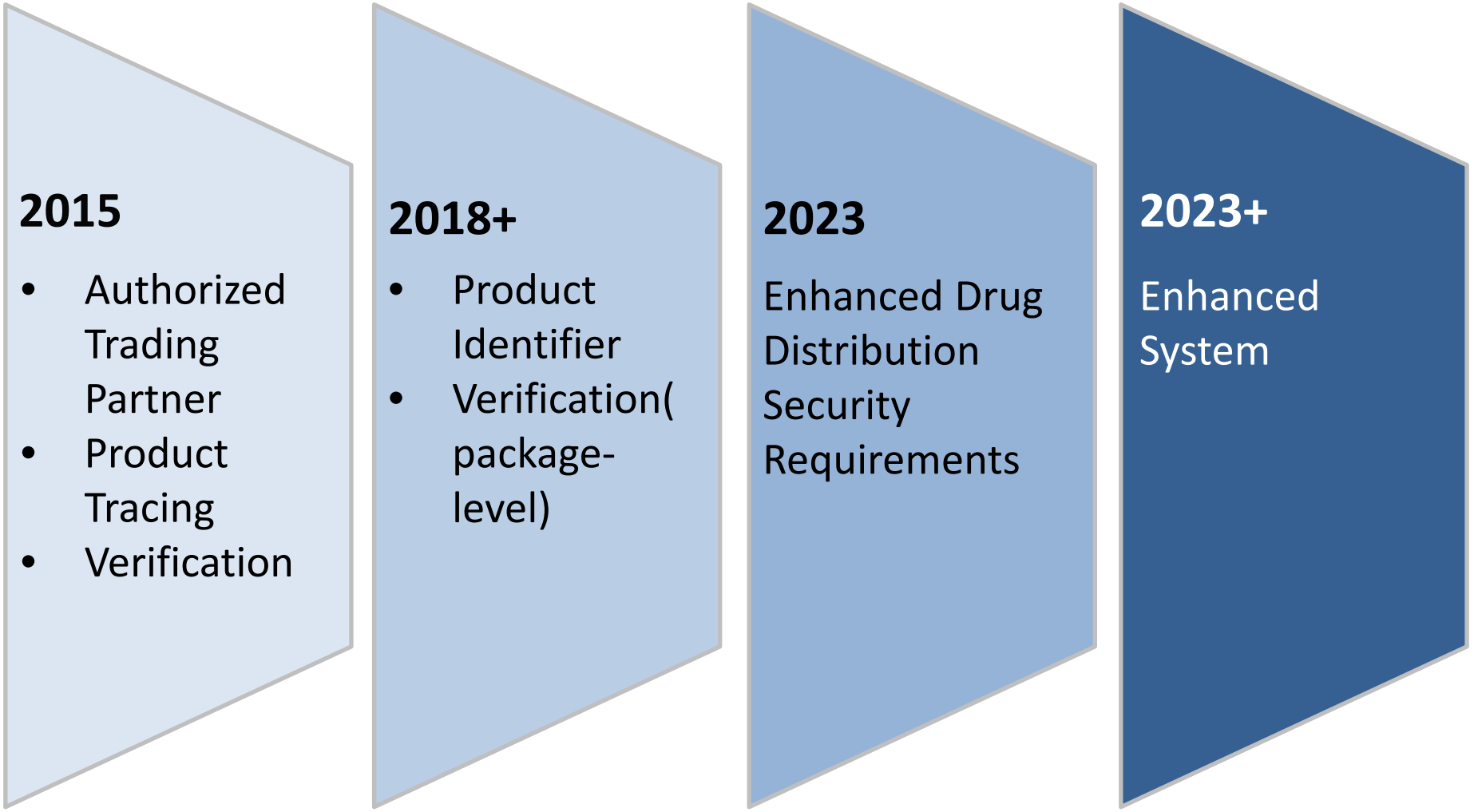
- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Human and machine readable formats

Machine readable barcodes:

- 2D data matrix for packages
- Linear or 2D data matrix for homogenous cases

DSCSA Implementation



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

DSCSA Implementation

2015

Authorized Trading Partners

- Manufacturers and Repackagers: valid registration with FDA
- WDDs & 3PLs: valid State or Federal license and compliance with reporting requirements
- Dispensers: valid State license

2015

Product Tracing

- Lot-level
- Provide and receive transaction documentation with each sale
- Respond to request for information
- Store records
- Paper and electronic formats

2015

Verification

- Quarantine and investigate suspect product
- Investigation illegitimate product
- Notify FDA and trading partners of illegitimate product
- Response to verification requests
- Store records

DSCSA Implementation

2018

Product Identification (Serialization)

- Manufacturers & repackagers encode product identifiers on prescription drug packages on the smallest individual saleable unit

Product Identifier: National Drug Code (NDC), Serial Number, Lot, Expiration Date)

2018+

Verification

- Serialized product can be verified down to the package level using the product identifier
- Saleable returns
- Compliance policies issued that provide additional time

DSCSA Implementation

2023

Enhanced Drug Distribution Security Requirements

- All electronic
- Enhanced product tracing at the package level (i.e., includes product identifier)
- Enhanced verification

2023 & Beyond

Enhanced System

- Enhanced drug distribution security
- Across the pharmaceutical supply chain
- Improved inspections and investigations
- Improved data analytics
- Continued compliance and enforcement

2023 Enhanced Drug Distribution Security Effective 11/27/2023

Section 582(g) Enhanced Drug Distribution Security -

(1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required-

(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of I nvestigating a suspect product or an illegitimate product; or

(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

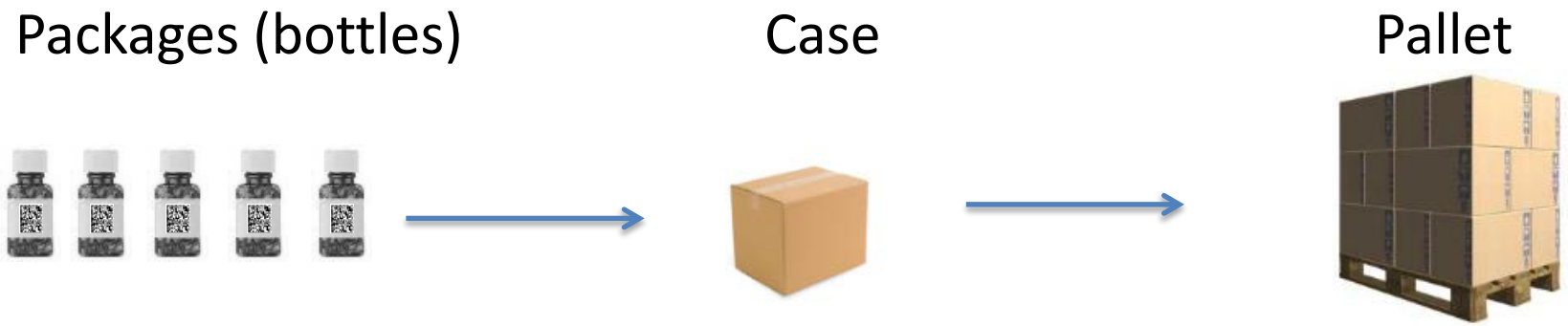
(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

System Attributes

- Transaction Information (TI) and Transaction Statement (TS) will be exchanged in a secure, interoperable, electronic manner…
- TI will include the product identifier at the package level for each package included in the transaction.
- Systems and processes for verification of product at the package level, including the standardized numerical identifier…which may include the use of aggregation and inference as necessary.
- Systems and processes necessary to promptly respond with the TI and TS for a product upon a request by FDA (or other appropriate Federal or State official) in the event of a recall or for investigating a suspect product or an illegitimate product
- Systems and processes necessary to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer, as applicable (upon a request by FDA…or an authorized trading partner…)
- Systems and processes in place to allow acceptance of saleable returns and only if such person can associate the saleable return product with the TI and TS associated with that product.

Aggregation and Inference

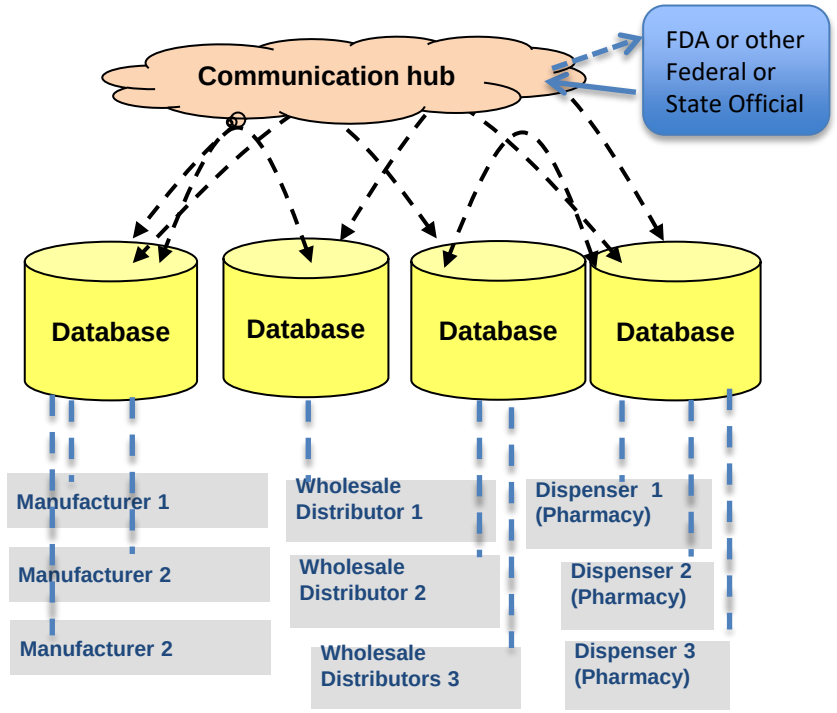
- Aggregation is the process of building a relationship between unique identifiers assigned to packaging containers.



- Inference involves examining information for a higher level of packaging to infer information about the next level of packaging and its contents.

System Structure

Semi - centralized Model

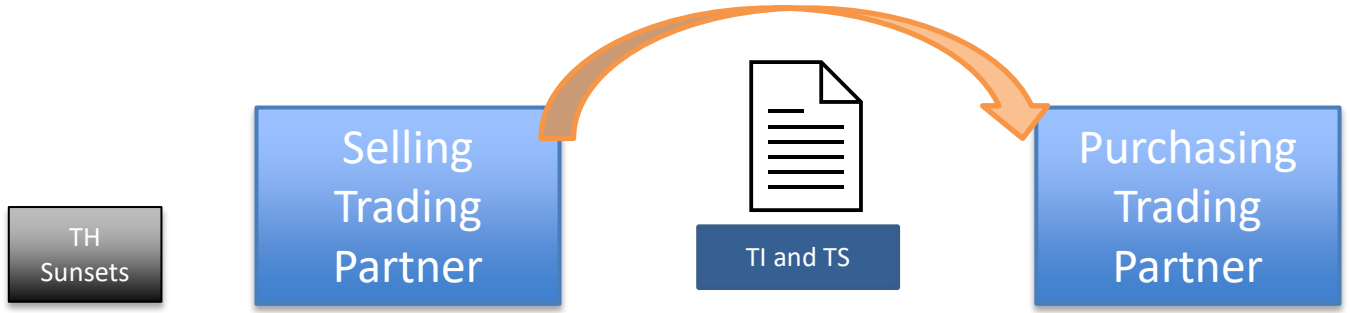


Centralized
- Trading partners provide data into a central repository (database)
- Product tracing and verification is performed by querying the central repository

Decentralized (or Distributed)
- Trading partners maintain their data in their own local database or a data storage provider's database
- Product tracing and verification is performed by querying the multiple databases
- A communications hub (active or passive) connects different databases

Semi – Centralized (or Semi – Distributed)
- Trading partners maintain data into a few centralized databases or data storage provider(s) database(s)
- Product tracing and verification is performed by querying the databases
- A communications hub connects different databases

Enhanced Product Tracing:
Exchange of Transaction Information & Statement



Beginning 11/27/2023 -

- Exchange of transaction information and transaction statements must be in a secure, interoperable, electronic manner

- Additional requirement to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer

Enhanced Product Tracing:
Serialized Transaction Information

Beginning 11/27/2023, the exchange of transaction information (TI) shall include the **product identifier** at the package level.

Pre-November 2023

Transaction Information:

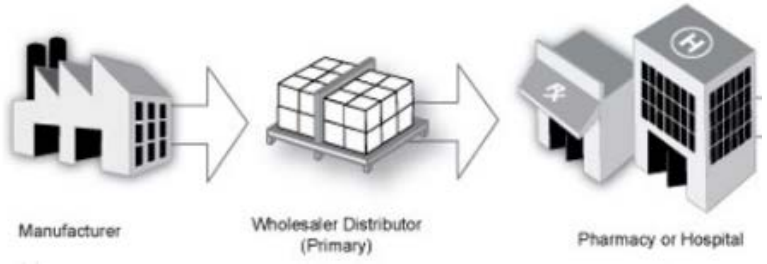
- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

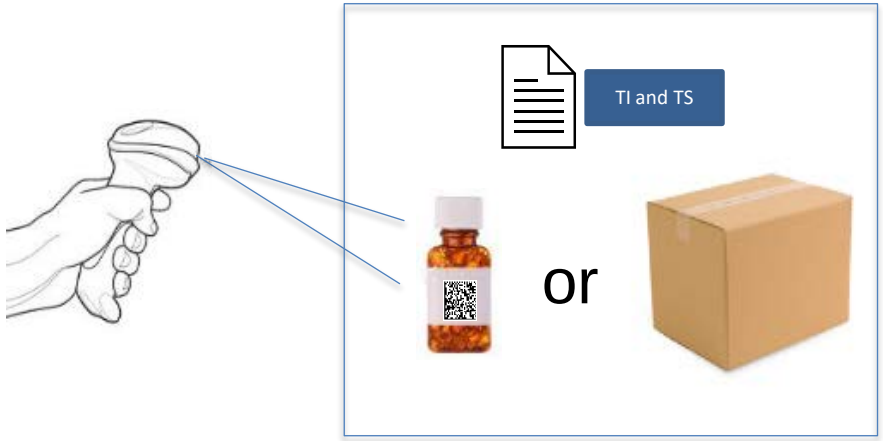
November 2023+

Transaction Information:

- 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
- Business name and address of the person from whom and to whom ownership is being transferred
- Serial number
- Expiration date

Enhanced Product Tracing:
Reconciliation of Data and Product





Selling Trading Partner

- Read product identifier (barcode) on the outbound package(s) or homogenous case(s) to fulfill an order
- Capture this data for the product tracing information (TI/TS) to be sent to the purchasing trading partner
- Provide data (TI/TS) and product(s) to purchasing trading partner

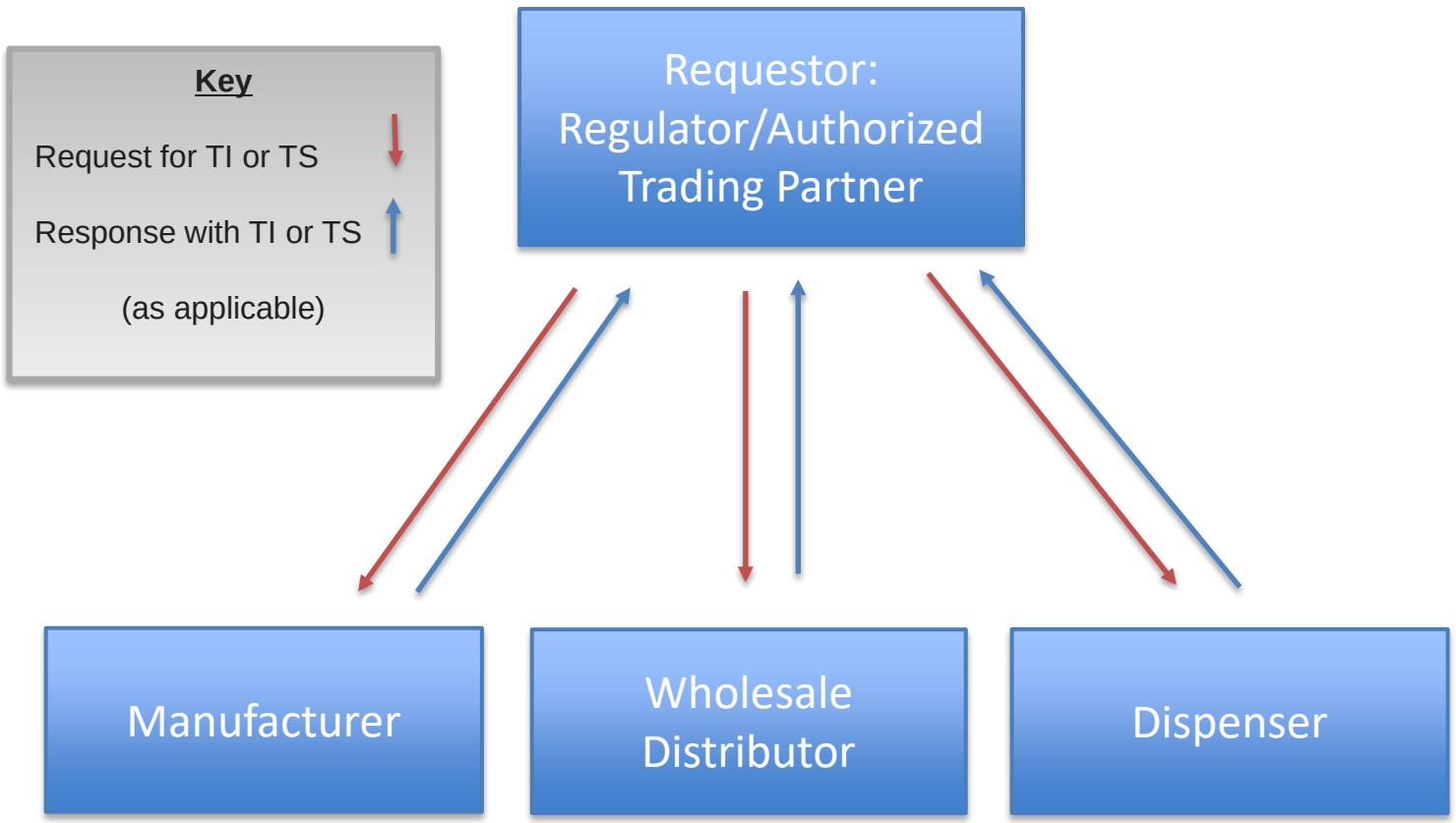
Purchasing Trading Partner

- Receive data (TI/TS) and product(s) from selling trading partner
- Read product identifier (barcode) on the inbound package(s) or homogenous case(s) received in an order
- Capture this data and reconcile with associated product tracing information (TI/TS) received from the selling trading partner

Enhanced Product Tracing: Handling Aggregation Errors & Other Discrepancies

- Product tracing information should be true, accurate, and complete.
- There may be a clerical error or discrepancy in product tracing information that may not be indicative of a suspect product.
- If a trading partner purchases product and identifies a potential clerical error or other discrepancy in product tracing information it received, that trading partner should resolve the error or discrepancy.
  - Immediately contact the trading partner that provided product tracing information
  - Do not sell product until the error or discrepancy has been resolved
  - If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, follow steps for verification if applicable (e.g., quarantine and investigation)

Gathering of Relevant Product Tracing Information

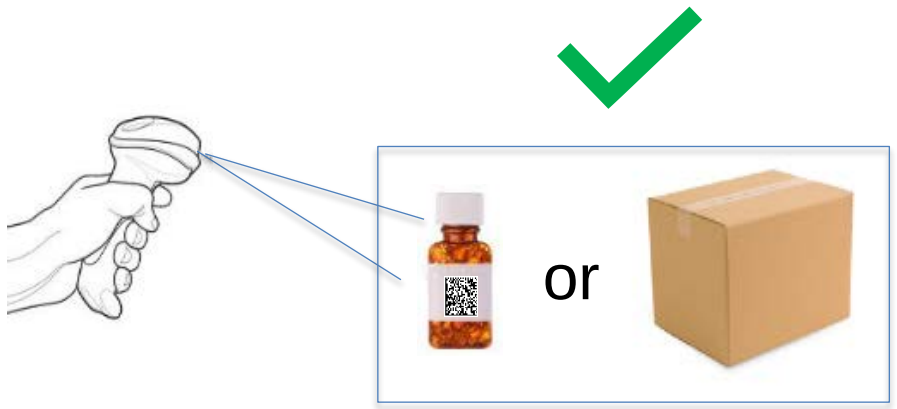


Under sections 582(g)(1)(D) and (E) of the FD&C Act:
...promptly respond with the TI and TS...upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required...

and

...promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer... (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

Enhanced Verification: Package-Level



Requestor: FDA/Authorized Trading Partner

Authorized Trading Partner

Key

Request for verification of the product identifier (including the NDC and serial number)

Response to verification request

Under section 582(g)(1)(C) of the FD&C Act: systems and processes for verification of product at the package level, including the standardized numerical identifier shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h)...which may include the use of aggregation and inference as necessary.

Enhanced Verification: Saleable Returns

Under Section 582(g)(1)(F) of the FD&C Act: Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

Effective
November 27, 2023

Enhanced Drug Distribution Security

Electronic

Interoperable

System across the pharmaceutical distribution supply chain

Stakeholder Presentations

The findings, conclusions, or recommendations in the following presentations are those of the authors and do not represent the U.S. Food and Drug Administration's position on any compliance requirement or endorsement of any particular technology or approach.

Reference herein to any specific commercial products, process, or service by trade name, trademark, manufacturer, or otherwise, does not constitute or imply an endorsement, recommendation, or favoring by the U.S. Food and Drug Administration. The views and opinions of authors should not be misconstrued as advertising products nor for endorsement purposes.

FDA Panel Participants

Abha Kundi	Regulatory Counsel CDER/OC/ODSIR
Connie Jung	Senior Advisor for Policy CDER/OC/ODSIR
Sridhar Mantha	Director CDER/Office of Strategic Programs/Office of Business Informatics
Katelyn Mineo	Regulatory Counsel CDER/Office of Regulatory Policy
Michael Bernstein	Director, Division of Regulatory Policy II CDER/Office of Regulatory Policy
Anita Richardson	Associate Director for Policy CBER/Office of Compliance and Biologics Quality
Christine Hunt	Regulatory Counsel FDA/Office of the Chief Counsel
Dinesh Kumar	Regulatory Counsel FDA/Office of the Chief Counsel

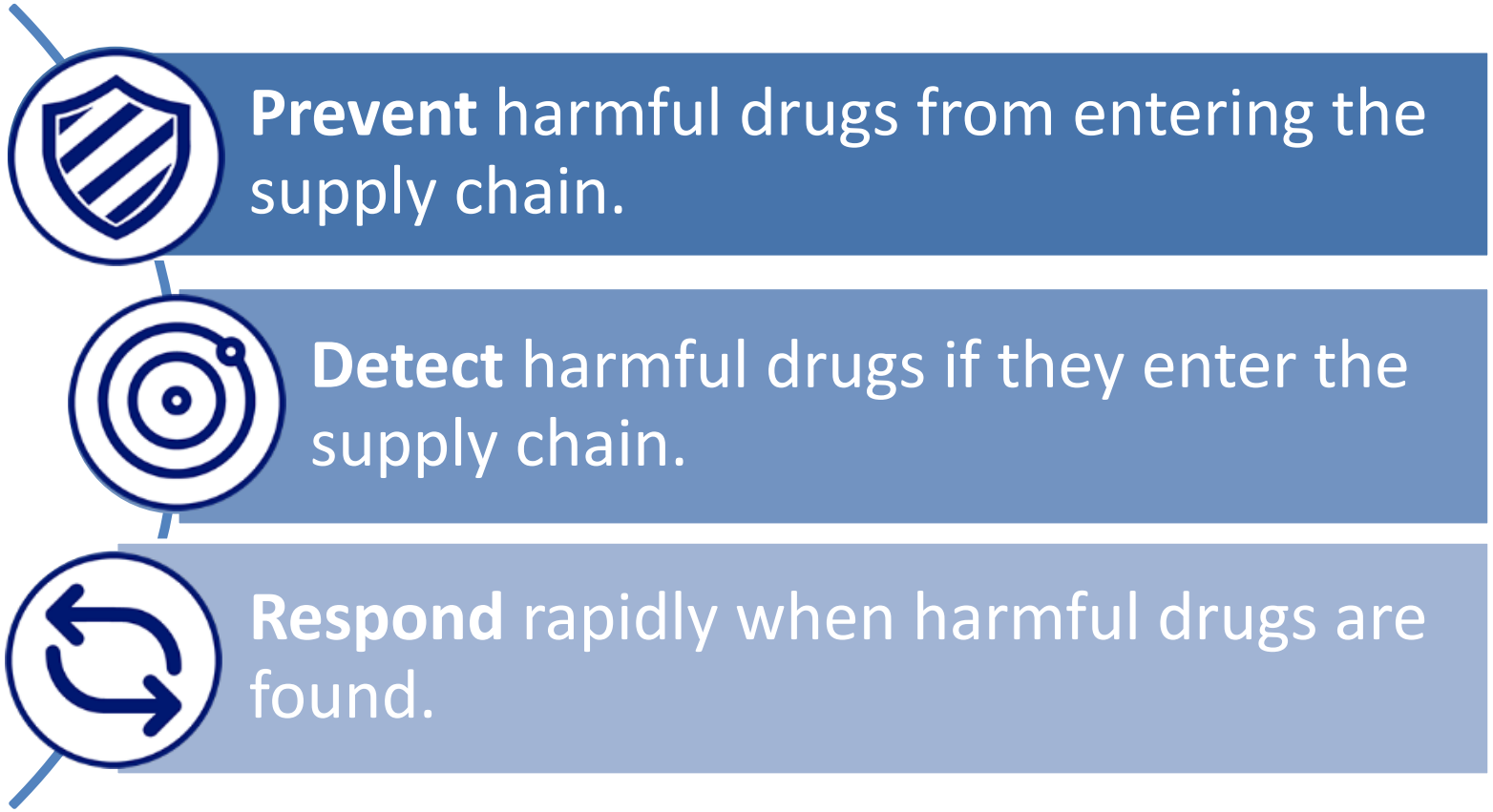
Enhanced Drug Distribution Security at the Package Level Under the DSCSA
FDA Public Meeting - November 16, 2021

FDA Questions to Speakers

Closing Remarks

Leigh Verbois, Ph.D.
Director
FDA/CDER/Office of Compliance
Office of Drug Security, Integrity and Response

How DSCSA Protects Patients



FDA Resources

- DSCSA main webpage

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

- DSCSA regulatory documents (i.e., regulations, guidances, federal register notices, pilot programs)

  https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm

Submit Comments to the Public Docket

- Submit either electronic or written comments on this public meeting [Docket No. FDA-2021-N-1004] by January 18, 2022.
- Follow instructions in the Federal Register Notice:

  https://www.federalregister.gov/documents/2021/10/15/2021-22474/enhanced-drug-distribution-security-at-the-package-level-under-the-drug-supply-chain-security-act