The DSCSA Implementation and Readiness Efforts for 2023 Virtual Public Meeting

FDA Public Meeting
December 7-8, 2022

Welcome

Michael M. Levy, JD

Deputy Director for Policy & Analysis

FDA/Center for Drug Evaluation and Research/Office of Compliance (OC)

Opening Remarks

Patrizia Cavazzoni, MD

Director

FDA/Center for Drug Evaluation and Research

The Drug Supply Chain Security Act DSCSA

- Enacted November 27, 2013
- Outlines steps to achieve interoperable, electronic tracing of product at the package level 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
- Establishes national licensure standards for wholesale drug distributors and third-party logistics providers (3PLs)

See FDA's DSCSA main webpage for more information: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Goal of the Public Meeting

To allow members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share their perspectives on DSCSA implementation and readiness efforts for 2023 requirements.

Meeting Logistics (1)

- All meeting attendees are in listen-only mode only (except speakers & moderators).
  - The chat should only be used for technical support.
- Attendees should 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 (2)

Oral Remarks from Stakeholders

- Selection to speak 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.
- FDA has limited the number of requests to present oral remarks based on the available time on the agenda.
- Selected speakers have been confirmed and will be presenting during their allotted time on the agenda.
- Speakers should avoid presenting any promotional material related to your organization.

Meeting Logistics (3)

Breakout sessions

- Smaller group discussion will occur in the afternoon of each day.
- Selections made represent stakeholders broadly.
- Concurrent breakout sessions will be discussing the same topics noted in the Federal Register notice.
- **Do not log out of the device during the lunch period so FDA can assign individuals to breakout rooms.**
- If selected for a breakout session, you will receive a notification in Zoom - accept this notification to be placed in a breakout room.
- Mute your device and turn off your camera during the lunch period.
- FDA will provide brief summaries to recap the salient points heard during breakout sessions to all attendees.

Meeting Logistics (4)

Open Session: Oral Remarks from Stakeholders

- To present oral remarks during the open session on Day 2 afternoon (after Breakout Session 3 is completed):
  - Email your request to speak in advance to CDERODSIRpublicmeetings@fda.hhs.gov by 4:00 PM (EST) of Day 1 (12/7/2022)
  - Include your full name, organization name, email address to be used to log into the meeting (if different)
- No requests will be taken on Day 2.
- If selected, you will receive an email confirmation by Day 2 (12/8/2022).
- On Day 2, please mute your device and turn off your camera until you are called upon to speak.
- FDA's AV team will unmute you at the time of the session.

Submit Comments to the Public Docket

- Submit either electronic or written comments on this public meeting [Docket No. FDA-2022-N-2671] by February 6, 2023.
- Follow instructions in the Federal Register Notice:

  Federal Register: Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration

Public Meeting: The Drug Supply Chain Security Act (DSCSA) Implementation and Readiness Efforts for 2023

Docket No. FDA-2022-N-2671

Wednesday December 7, 2022: 10:00 am – 3:00 pm EST

AGENDA*

10:00 am	Welcome	Michael M. Levy, JD *Deputy Director for Policy & Analysis* *Office of Compliance (OC), Center for Drug Evaluation and Research (CDER)*
10:00 am – 10:10 am	Opening Remarks	Patrizia Cavazzoni, MD *Center Director, CDER*
10:10 am – 10:20 am	Goals of the Public Meeting and Logistics	Dan Bellingham *Policy Analyst* *Division of Supply Chain Integrity (DSCI), Office of Drug Security, Integrity and Response (ODSIR), OC, CDER*
10:20 am – 10:30 am	DSCSA Public Private Partnership	Connie Jung, RPh, PhD *Senior Advisor for Policy* *ODSIR, OC, CDER* Eric Marshall *Executive Director, Partnership for DSCSA Governance (PDG)*
10:30 am – 11:00 am	*Oral Remarks from Stakeholders – Group A*	Moderated by Dan Bellingham
11:00 am – 11:15 am	Break	
11:15 am – 11:50 am	*Oral Remarks from Stakeholders – Group B*	
11:50 am – 12:05 pm	Overview of Standards for the Interoperable Exchange of Information	Abha Kundi, JD, MPH *Team Lead* *DSCI, ODSIR, CDER, OC* Lysette Deshields, PharmD, JD *Regulatory Counsel* *DSCI, ODSIR, CDER, OC*
12:05 pm – 1:05 pm	Break	

(Day 1 – Continued)

1:05 pm – 1:15 pm	Breakout Session Logistics and Topics	Lysette Deshields
1:15 pm – 2:00 pm	Breakout Session 1 • DSCSA standards for the interoperable data exchange of product tracing information for enhanced product tracing and verification • FDA requests to trading partners for product tracing information, verification for the purpose of investigations of suspect or illegitimate products, or recalls to support enhanced drug distribution requirements under section 582(g) of the FD&C Act	
2:00 pm – 2:20 pm	*Break*	
2:20 pm – 2:55 pm	Breakout Session 2 • Steps taken by the pharmaceutical distribution supply chain to build capacity for package-level tracing, including the ability of the health care system to maintain patient access to medicines, scalability of DSCSA requirements, and best practices • General impact that the DSCSA requirements would have on public health including patient safety and access to prescription drugs and on stakeholders, in terms of costs, benefits, and regulatory burden	
2:55 pm – 3:00 pm	Closing Remarks	Dan Bellingham
3:00 pm	Adjourn Day 1	

Thursday, December 8, 2022: 10:00 am – 3:00 pm EST

AGENDA*

10:00 am	Welcome	Tia Harper-Velazquez, PharmD, JD, *Division Director* *Division of Supply Chain Integrity (DSCI), Office of Drug Security, Integrity and Response (ODSIR), OC, CDER*
10:00 am – 10:10 am	Opening Remarks	Leigh Verbois, PhD *Director*
10:10 am – 10:15 am	Goals of the Public Meeting Day 1 Recap	Tia Harper-Velazquez
10:15 am – 10:25 am	Meeting Logistics	Kelli Dobilas *Branch Chief* *DSCI, ODSIR, OC, CDER*
10:25 am – 11:05 am	*Oral Remarks from Stakeholders – Group C*	Moderated by Kelli Dobilas
11:05 am – 11:15 am	*Break*	
11:15 am – 12:00 pm	*Oral Remarks from Stakeholders – Group D*	
12:00 pm – 1:00 pm	*Break*	
1:00 pm – 1:15 pm	Overview of Enhanced Drug Distribution Security Requirements	Abha Kundi Connie Jung
1:15 pm – 1:20 pm	Breakout Session Logistics and Topics	Abha Kundi
1:20 pm – 2:05 pm	Breakout Session 3 • Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023 • Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level	
2:05 pm – 2:20 pm	*Break*	
2:20 pm – 2:50 pm	*Open Session: Oral Remarks from Stakeholders*	
2:50 pm – 3:00 pm	Day 2 Recap and Closing Remarks	Connie Jung
3:00 pm	Adjourn	

DSCSA Public Private Partnership

Connie Jung, Senior Advisor for Policy
FDA/CDER/OC/Office of Drug Security, Integrity and Response

Eric Marshall, Executive Director
Partnership for DSCSA Governance (PDG)

DSCSA Public Private Partnership

- Public Private Partnerships (PPPs)
- DSCSA PPP - FDA and the Partnership for DSCSA Governance (PDG) engagement

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-public-private-partnership

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders – Group A

Moderated by: Dan Bellingham

FDA/CDER/OC/ODSIR

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Brian Rezach

Association for Accessible Medicines (AAM)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Ryan Kaat

Pharmaceutical Research and Manufacturers of America (PhRMA)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Gurdeep Sidhu

Apotex

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Break

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders – Group B

Moderated by: Dan Bellingham

FDA/CDER/OC/ODSIR

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Eric Marshall

Partnership for DSCSA Governance (PDG)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Robert Celeste

Dave Mason

Max Peoples

Open Credentialing Initiative (OCI)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Pat O'Connor

International Warehouse Logistics Association (IWLA)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Mark Hendrickson

Pharmaceutical Distribution Security Alliance (PDSA)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Break

We will restart at 1:05 pm (EST)

For breakout sessions - DO NOT log out of the device during the lunch period so FDA can assign individuals to rooms.

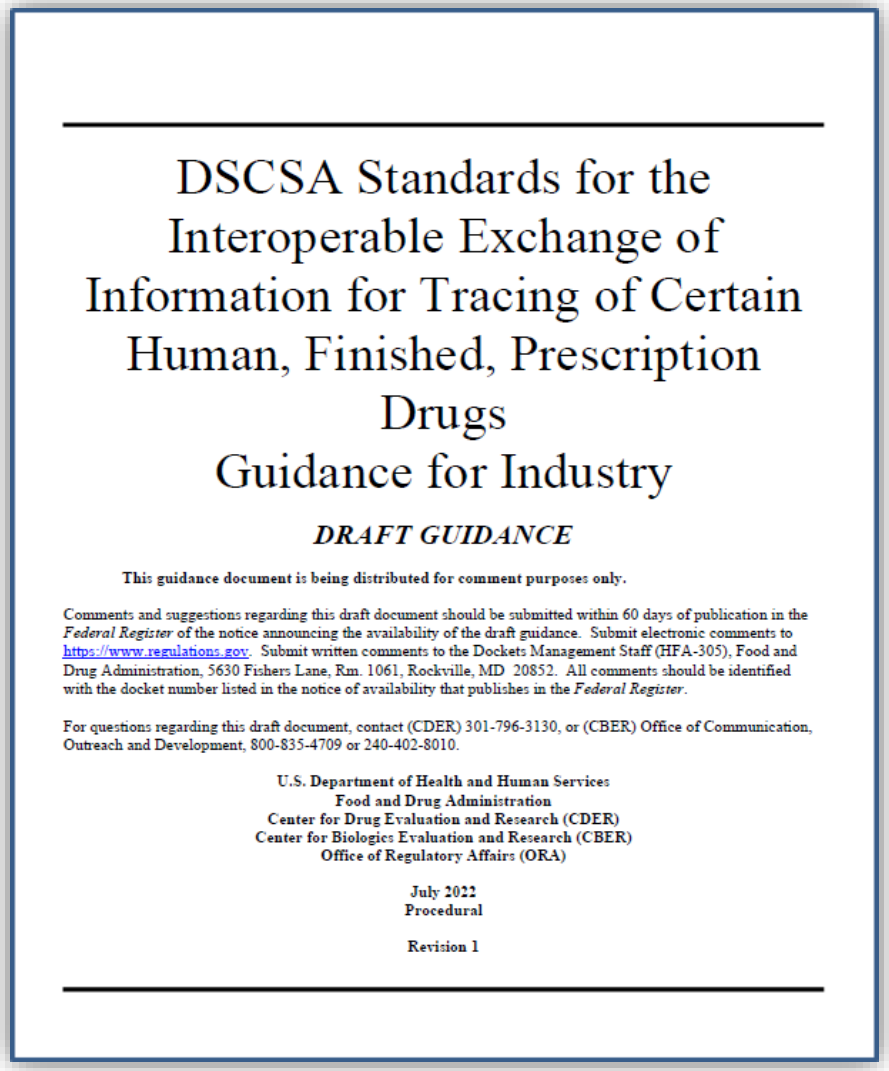
Overview of Standards for the Interoperable Exchange of Information for Tracing

Abha Kundi

Lysette Deshields

FDA/CDER/OC/Office of Drug Security, Integrity and Response

Standards for Interoperable Exchange



DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs
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 (HFA-305), 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) 301-796-3130, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

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)

July 2022
Procedural

Revision 1

- Updates the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required
- FDA recommends GS1's Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with transaction information and transaction statements.
- FDA recognizes there are a variety of technological approaches available to trading partners to comply with enhanced drug distribution security requirements (section 582(g)(1) of the FD&C Act) and does not expect all trading partners to rely upon a single technological approach.

Breakout Session Logistics

- Breakout session participants:
  - selected for broad representation of stakeholders in smaller group discussions
  - have been assigned to a breakout room and will receive a notification in Zoom - accept this notification to be placed in a room
  - should mute yourself when not speaking, and you will be able to unmute yourself to speak
- The breakout sessions will cover the same topics at the same time.
- FDA representatives will facilitate discussion and capture participant input.

****

All other public meeting attendees will remain in the general meeting session until the breakout sessions are completed.

Breakout Session 1 - Topics

- DSCSA standards for the interoperable data exchange of product tracing information for enhanced product tracing and verification
- FDA requests to trading partners for product tracing information, verification for the purpose of investigations of suspect or illegitimate products, or recalls to support enhanced drug distribution requirements under section 582(g) of the FD&C Act

****

All other public meeting attendees will remain in the general meeting session until the breakout sessions are completed.

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 7, 2022

Break

Breakout Session 2 - Topics

- Steps taken by the pharmaceutical distribution supply chain to build capacity for package-level tracing, including the ability of the health care system to maintain patient access to medicines, scalability of DSCSA requirements, and best practices
- General impact that the DSCSA requirements would have on public health including patient safety and access to prescription drugs and on stakeholders, in terms of costs, benefits, and regulatory burden

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Reminder

Open Session: Oral Remarks from Stakeholders

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- No requests will be taken on Day 2.
- If selected, you will receive an email confirmation by Day 2 (12/8/2022).
- On Day 2, please mute your device and turn off your camera until you are called upon to speak.
- FDA's AV team will unmute you at the time of the open session.

Closing Remarks

The DSCSA Implementation and Readiness Efforts for 2023 Virtual Public Meeting

FDA Public Meeting
December 7-8, 2022

Welcome and Opening Remarks

Tia Harper Velazquez, PharmD, JD

Division Director

Division of Supply Chain Integrity

Office of Drug Security, Integrity and Response

FDA/CDER/Office of Compliance

Goal of the Public Meeting

To allow members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share their perspectives on DSCSA implementation and readiness efforts for 2023 requirements.

Recap – Day 1

- There has been industry progress, but there is still work to be done before 2023 deadline
- Testing and piloting still needs to be done before November 2023
- Many plan to use EPCIS as the standard for data exchange, but there is a need to have flexible methods, such as the use of data portals and email, that may fill the need by smaller entities.
- Challenge: No way to anticipate the volume or number of "trace" requests or verification requests (from FDA or other Federal or State official) or from another trading partner
- Challenge: Onboarding and connectivity with suppliers and customers
- Challenge: Data quality, consistency, alignment, errors

- Need guidance on how trading partners should handle product in their warehouses that do not have serialized transaction information as of 11/27/2023
- Need to standardize how industry handles exceptions processing and clerical errors
- Need appropriate flexibility from FDA to resolve clerical errors to ensure drugs can continue to move
- Continue outreach to trading partners, as lack of understanding of complexities and needs may still exist, particularly with small entities
- Seeking better understanding of how FDA (and other Federal or State official) will make requests for DSCSA information from trading partners
- How will industry know it is receiving an authentic request from a trading partner or a regulator

For discussion purposes – Not an exhaustive list

Agenda

Thursday, December 8, 2022: 10:00 am – 3:00 pm EST

AGENDA

10:00 – 10:15 am	Welcome, Opening Remarks and Goal of the Public Meeting	Tia Harper-Velazquez, PharmD, JD, *Division Director* *Division of Supply Chain Integrity (DSCI), Office of Drug Security, Integrity and Response (ODSIR), OC, CDER*
10:15 am – 10:25 am	Day 1 Recap and Meeting Logistics	Kelli Dobilas *Branch Chief* *DSCI, ODSIR, OC, CDER*
10:25 am – 11:05 am	*Oral Remarks from Stakeholders – Group C*	Moderated by Kelli Dobilas
11:05 am – 11:15 am	***Break***	
11:15 am – 12:00 pm	*Oral Remarks from Stakeholders – Group D*	
12:00 pm – 1:00 pm	***Break***	
1:00 pm – 1:15 pm	Overview of Enhanced Drug Distribution Security Requirements	Connie Jung
1:15 pm – 1:20 pm	Breakout Session Logistics and Topics	Connie Jung
1:20 pm – 1:30 pm	*Transition to Breakout Room*	
1:30 pm – 2:15 pm	Breakout Session 3 • Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023 • Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level	
2:15 pm – 2:25 pm	***Break***	
2:25 pm – 2:30 pm	Day 2 Recap and Closing Remarks	Connie Jung
2:30 pm	Adjourn	

Meeting Logistics (1)

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Meeting Logistics (3)

Breakout sessions

- Smaller group discussion in the afternoon of each day
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- Concurrent breakout sessions will be discussing the same topics noted in the Federal Register
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- FDA will provide brief summaries to recap the salient points heard during breakout sessions to all attendees

Meeting Logistics (4)

Agenda Update

- No Open Session - Since no requests were received to present oral remarks during the open session on Day 2, we will cancel the open session on the agenda.
- The agenda will be modified to start the Day 2 Recap and Closing Remarks at 2:20 pm (EST) and the meeting will adjourn early.

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders Session - Group C

Moderated by: Kelli Dobilas, Branch Chief

FDA/CDER/OC/ODSIR

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Anita Ducca

Healthcare Distribution Alliance (HDA)

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Scott Mooney

McKesson Corporation

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Brad Pine

J M Smith Corporation

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Matt Sample

AmerisourceBergen

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Break

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders Session - Group D

Moderated by: Kelli Dobilas, Branch Chief

FDA/CDER/OC/ODSIR

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Josh Bolin

National Association of Boards of Pharmacy

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Allan Bowyer

TraceLink

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Sean Lockhead

Innovit

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Break

We will restart at 1:00 pm (EST)

Overview of Enhanced Drug Distribution Security Requirements

Connie Jung

FDA/CDER/OC/Office of Drug Security, Integrity and Response

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

2023+

Enhanced Drug Distribution Security Requirements

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

Enhanced Drug Distribution Security Effective 11/27/2023

Section 582(g) of the FD&C Act

(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 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).

(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.

2023 Enhanced Drug Distribution Security Effective 11/27/2023

2023+

Enhanced Drug Distribution Security Requirements

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

Enhanced Product Tracing

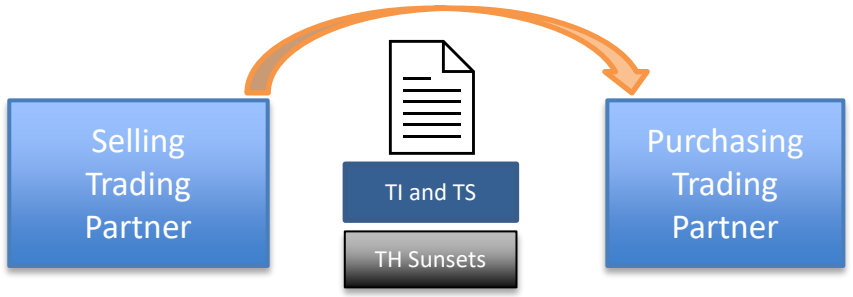
- Exchange of transaction information (TI) and transaction statement (TS)
- Gathering of relevant product tracing information in response to requests…
- Serialized TI

Enhanced Verification

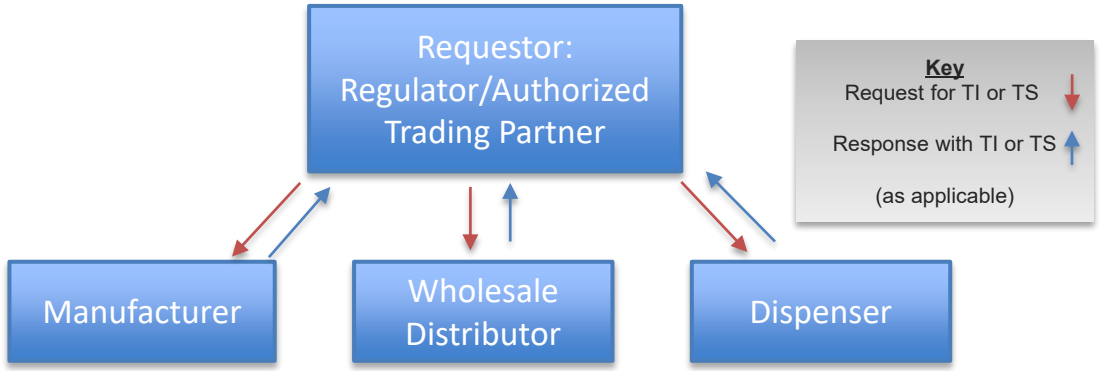
- Package-level
- Saleable Returns

Enhanced Product Tracing

Beginning 11/27/2023 - Exchanging and Responding to Request for Product Tracing Information



Transaction information (TI) and the transaction statements (TS)…shall be exchanged in a secure, interoperable, electronic manner…
[Section 582(g)(1)(A) 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
[Section 582(g)(1)(D) of the FD&C Act]

Promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable…
[Section 582(g)(1)(E) of the FD&C Act]

Enhanced Product Tracing

Beginning 11/27/2023 - Serialized Transaction Information

Transaction information…shall include the product identifier at the package level for each package included in the transaction. *[Section 582(g)(1)(B) of the FD&C Act]*

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

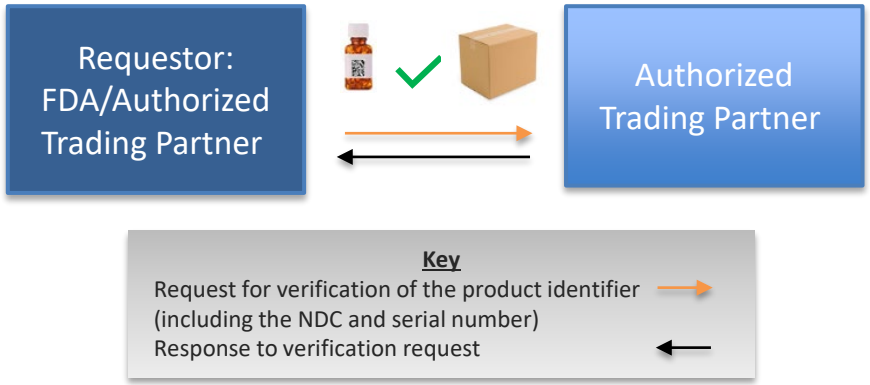
November 2023+

Transaction Information:

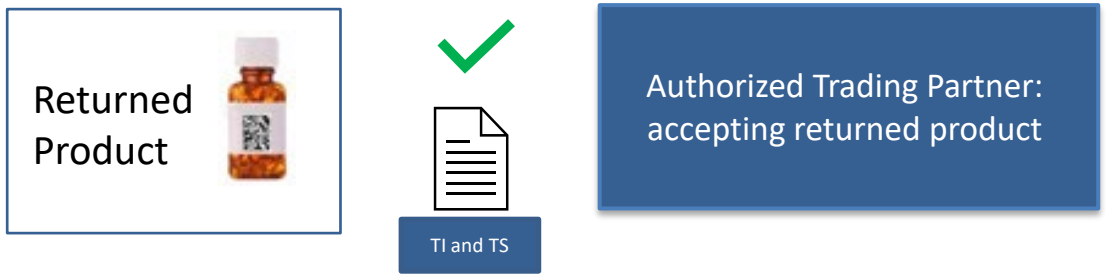
- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of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

Enhanced Verification

Beginning 11/27/2023 - Package-Level and Saleable Returns



Systems and processes for verification of product at the package level, including the standardized numerical identifier…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.
[Section 582(g)(1)(C) 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.

[Section 582(g)(1)(F) of the FD&C Act]

Breakout Session Logistics

- Breakout session participants:
  - selected for broad representation of stakeholders in smaller group discussion
  - Must log out of general session and use the link provided in the email to enter the breakout room
  - should mute yourself when not speaking, and you will be able to unmute yourself to speak
- The breakout sessions will cover the same topics at the same time.
- FDA representatives will facilitate discussion and capture participant input.

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All other public meeting attendees will remain in the general meeting session until the breakout sessions are completed.

Breakout Session 3 - Topics

- Stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023
- Technical capabilities and legal authorities, if any, needed to establish interoperable, electronic product tracing at the package level

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All other public meeting attendees will remain in the general meeting session until the breakout sessions are completed.

DSCSA Implementation and Readiness Efforts for 2023
Public Meeting – December 8, 2022

Break

Reminder

- Submit either electronic or written comments on this public meeting [Docket No. FDA-2022-N-2671] by February 6, 2023.

  Follow instructions in the Federal Register Notice:

  Federal Register: Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments

- Meeting materials and recording will be posted on the public meetings webpage

Day 2 Recap and Closing Remarks