The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

Virtual Public Meeting

December 8-9, 2020

Opening Remarks

Patrizia Cavazzoni, M.D.
Acting Director of the
Center for Drug Evaluation and Research
(CDER)

Goals of the Meeting

To further inform FDA's development of the enhanced drug distribution security provisions of the DSCSA

Day 1

- Learn about key findings and lessons learned from participants in FDA's DSCSA Pilot Project Program
- Learn about other pilot projects outside of our program
- Discuss relevant results from pilot projects

Day 2

- Provide key concepts regarding enhanced drug distribution security
- Discuss enhanced product tracing and verification strategies and issues

Meeting Logistics

Main Meeting	Breakout Sessions
• Use the main meeting link provided in your registration confirmation email (Adobe) for both days to view slides. • For Speakers and Moderators: Dial in separately by phone (select the phone icon at the top left for the dial-in information). Mute your computer audio to avoid feedback. • For attendees: Use your computer audio to listen. No separate dial-in is needed.	• Use the breakout session links provided by email to join Webex meeting; different links will be provided for Day 1 and Day 2. • Webex will prompt to call your phone or computer. • Please mute your phone when not speaking.
- All meeting attendees - Listen-only mode (except Speakers & Moderators) - Attendees can use the chat box for questions when prompted by Moderator during the panel Q&A.	- Smaller groups of attendees selected for broad representation of stakeholders in discussions. - FDA representatives will facilitate discussion and capture participant input. - Attendees will be assigned to Breakout Session A or B. - Breakout Sessions A & B will cover the same topics. - Attendees will be able to unmute phones to speak. - High-level reports from the Breakout Sessions will be provided during the main meeting.

- Information captured in discussions will be aggregated and not associated with a specific individual or company.
- Concepts and Terminology document is provided for discussion purposes and should not be interpreted as legal or regulatory definitions or guidance.

U.S. Food and Drug Administration

Public Meeting: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

Docket No. FDA-2020-N-1862

Tuesday, December 8, 2020: 9:00 am – 4:00 pm

AGENDA

9:00 am	Welcome	Connie Jung, RPh, PhD *Senior Advisor for Policy, Office of Drug Security, Integrity, and Response (ODSIR), Office of Compliance (OC), Center for Drug Evaluation and Research (CDER)*
9:05 am – 9:15 am	Opening Remarks	Patrizia Cavazzoni, MD *Acting Center Director, CDER*
9:15 am – 9:20 am	Goals of the Public Meeting and Logistics	Connie Jung
9:20 am – 9:35 am	Overview of FDA's DSCSA Pilot Project Program	Dan Bellingham *Policy Analyst, ODSIR, OC, CDER*
9:35 am – 9:45 am	Partnership for DSCSA Governance	Matthew Price
9:45 am – 9:55 am	ICON INDICES	Anurag Saxena
9:55 am – 10:05 am	Tracelink	Brian Daleiden
10:05 am – 10:15 am	The Optimal Solution	Dwight de Vera
10:15 am – 10:25 am	Sanofi	Arthi Nagaraj
10:25 am – 10:35 am	GS1 US	Peter Sturtevant
10:35 am – 10:50 am	Participant Panel Q&A	Dan Bellingham (Moderator)
10:50 am – 11:00 am	Break	
11:00 am – 11:10 am	Providence Health Technologies	Todd Barrett
11:10 am– 11:20 am	Franciscan Missionaries of Our Lady Health System	Chris Chandler
11:20 am – 11:30 am	AmerisourceBergen/Xavier	Matt Sample

U.S. Food and Drug Administration

Public Meeting: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

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11:30 am – 11:40 am	LedgerDomain	Ben Taylor
11:40 am – 11:50 am	MediLedger	Eric Garvin
11:50 am – 12:05 pm	Participant Panel Q&A	Dan Bellingham (Moderator)
12:05 pm – 1:05 pm	**Lunch Break**	
1:05 pm – 1:15 pm	Rymedi	Jason Cross
1:15 pm – 1:25 pm	KitCheck	Tim Kress-Spatz
1:25 pm – 1:35 pm	IBM	Mark Treshock
1:35 pm – 1:45 pm	IDLogiq	Kelly Nguyen
1:45 pm – 1:55 pm	LSPediA	Riya Cao
1:55 pm – 2:05 pm	Participant Panel Q&A	Dan Bellingham (Moderator)
2:05 pm – 2:20 pm	**Break**	
2:20 pm – 2:45 pm	Other Pilot Activities	Dan Bellingham (Moderator)
2:45 pm – 3:10 pm	Breakout Session A: Methods for Enhanced Product Tracing and Verification	
3:10 pm – 3:20 pm	**Break**	
3:20 pm – 3:45 pm	Breakout Session B: Methods for Enhanced Product Tracing and Verification	
3:45 pm – 3:55 pm	Recap	Connie Jung
3:55 pm – 4:00 pm	Closing Day 1	Leigh Verbois, PhD *Director, Office of Drug Security, Integrity, and Response, OC, CDER*

DSCSA Pilot Project Program Goals

- Identify the system attributes needed to implement the requirements of section 582, particularly the requirement to utilize a product identifier for product tracing and verification purposes; and
- Assess the ability of supply chain members to:
  - satisfy the requirements of section 582 of the FD&C Act;
  - identify, manage, and prevent the distribution of suspect and illegitimate products as defined in section 581(21) and 581(8) of the FD&C Act, respectively; and
  - exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner

DSCSA Pilot Project Program

FDA intends to make the following information about each pilot project of the program available to the public on FDA's website in a final program report:

- The names and industry sector(s) of the pilot project participant(s);
- the pilot project's objectives and evaluation methods;
- the duration of the pilot project; and
- the key findings and lessons learned from the pilot project

Updates can be found at FDA's webpage: DSCSA Pilot Project Program https://www.fda.gov/drugs/drug-supply-chain-security-actdscsa/dscsa-pilot-project-program

DSCSA Pilot Project Program

- Explore and evaluate methods to enhance the safety and security of the drug supply chain
- Selected participants reflects the diversity of the supply chain including large and small entities from all industry sectors
- Selection into this program 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 other approach used in a pilot project.

DSCSA Pilot Project Program Participants (1)

Project Leads	Pilot Project Title
AmerisourceBergen/Xavier Health	AmerisourceBergen Xavier Health End-to-End 2023 Proof of Concept Pilot
Cardinal Health	Interoperability Data Exchange Errors and Exception Handling
Franciscan Missionaries of Our Lady Health System (FMOLHS)	DSCSA Verification to Improve Product Traceability at FMOL Health System
GS1	Barcode Readability for DSCSA 2023 Interoperability
IBM/KPMG/Merck/Walmart	DSCSA Blockchain interoperability Pilot
ICON INDICES	Enterprise Serialization Architecture of Point-To-Point Network System
IDLogiq	IDLogiq Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment
KitCheck	Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies
LSPediA	Router Service Solution for Verification/Notification and Interoperability 2023
MediLedger	MediLedger DSCSA Pilot

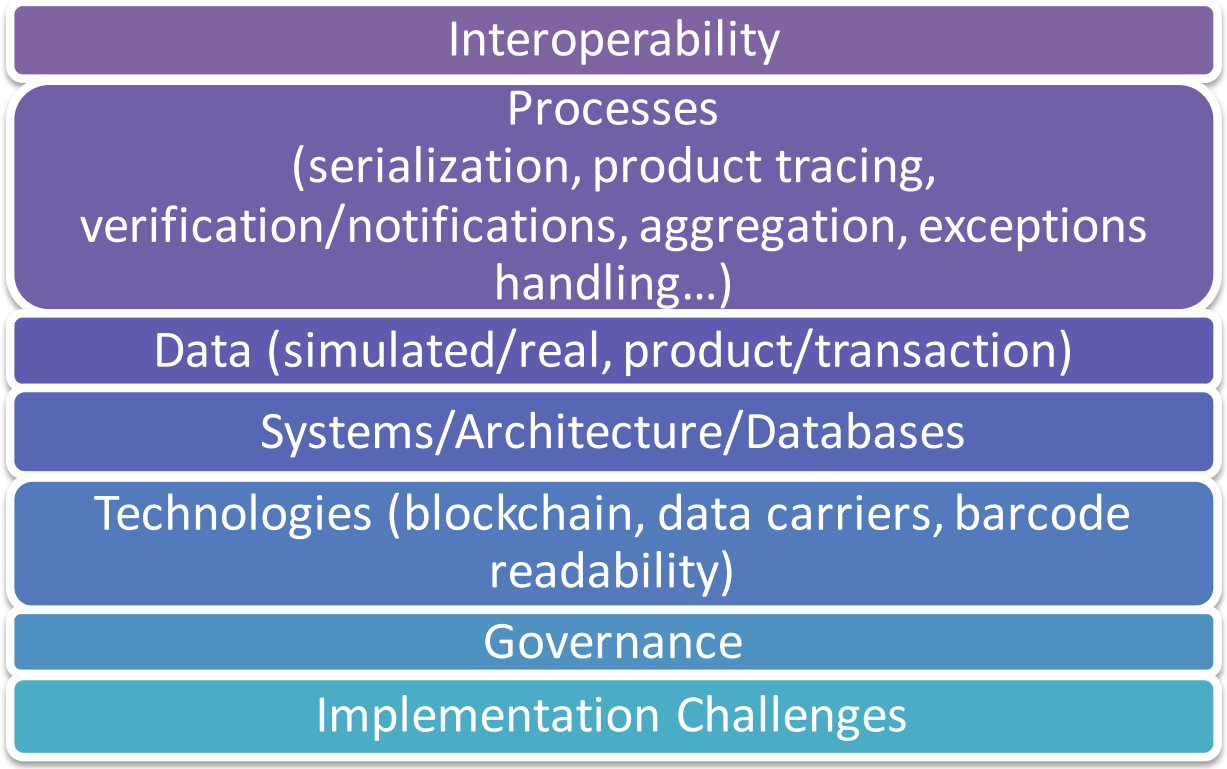
(NOTE: Some projects involve partnering entities that are not listed in the table.)

DSCSA Pilot Project Program Participants (2)

Project Leads	Pilot Project Title
Optel	Improved end-to-end drug supply chain traceability with OPTEL's Intelligent Supply ChainTM technologies
The Optimal Solution	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Pharmaceutical Distribution Security Alliance (PDSA)	DSCSA Governance Processes
PriMed Pharmaceuticals	Secondary Wholesaler Challenges During Implementation of DSCSA Required Track & Trace Platforms
Providence Health Technologies (PHT)	FDA Small Dispenser Pilot Study
rfxcel	rfxcel Verification/Notification Readiness & Extensibility Pilot
Rymedi	DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers
Sanofi	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
TraceLink	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
UCLA Health	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology

(NOTE: Some projects involve partnering entities that are not listed in the table.)

DSCSA Pilot Projects



DSCSA Pilot Project Program

Participant Results (1)

Program Participant/Speaker *(All partnering entities are not listed)*	Pilot Project
Partnership for DSCSA Governance (PDG)/Matthew Price	DSCSA Governance Processes
ICON INDICES Anurag Saxena	Enterprise Serialization Architecture of Point-To-Point Network System
Tracelink Brian Daleiden	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
The Optimal Solution Dwight de Vera	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Sanofi Arthi Nagaraj	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
GS1 US Peter Sturtevant	Barcode Readability for DSCSA 2023 Interoperability

We will have a Participant Panel Q&A after the above presentations.

DSCSA Pilot Project Program

Participant Results (1)

Program Participant/Speaker *(All partnering entities are not listed)*	Pilot Project
Partnership for DSCSA Governance (PDG)/Matthew Price	DSCSA Governance Processes
ICON INDICES Anurag Saxena	Enterprise Serialization Architecture of Point-To-Point Network System
Tracelink Allan Bowyer	DSCSA Traceability with Distributed Ledgers and Digital Recalls Project Proposal
The Optimal Solution Dwight de Vera	The Optimal Solution a Federated Approach to Designing the Interoperable DSCSA
Sanofi Arthi Nagaraj	Product Identifier Verifications by a Contract Manufacturing Organization on behalf of a Manufacturer Authorization Holder
GS1 US Peter Sturtevant	Barcode Readability for DSCSA 2023 Interoperability

Participant Panel Q&A

- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.

Break

We will reconvene in 10 minutes.

DSCSA Pilot Project Program

Participant Results (2)

Program Participant/Speaker *(All partnering entities are not listed)*	Pilot Project
Providence Health Technologies/Todd Barrett	Small Dispenser Pilot Study
Franciscan Missionaries of Our Lady Health System/Chris Chandler	DSCSA Verification to Improve Product Traceability at FMOL Health System
AmerisourceBergen/Xavier Health/Matt Sample	End-to-End 2023 Proof of Concept Pilot
UCLA/LedgerDomain Ben Taylor	UCLA-LedgerDomain: DSCSA Solution Through Blockchain Technology
MediLedger Eric Garvin	MediLedger DSCSA Pilot

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DSCSA Pilot Project Program

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MediLedger Eric Garvin	MediLedger DSCSA Pilot

Participant Panel Q&A

- Please type in your question for the panel into the chat box.
- FDA will select and direct questions to the panel.

Lunch Break

We will reconvene in 1 hour.

DSCSA Pilot Project Program

Participant Results (3)

Program Participant/Speaker *(All partnering entities are not listed)*	Pilot Project
Rymedi Jason Cross	DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers
KitCheck Tim Kress-Spatz	Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies
IBM/KPMG/Merck/Walmart Mark Treshock	DSCSA Blockchain interoperability Pilot
IDLogiq Kelly Nguyen	IDLogiq Next Generation Advanced REAL FIPS-Compliant Cryptographic ID Authentication with Transaction Ledger Powered by Blockchain/Distributed Ledger Technology for Decentralized Heterogeneous Global Network Computing Environment
LSPediA Riya Cao	Router Service Solution for Verification/Notification and Interoperability 2023

We will have a Participant Panel Q&A after the above presentations.

DSCSA Pilot Project Program

Participant Results (3)

Program Participant/Speaker *(All partnering entities are not listed)*	Pilot Project
Rymedi Jason Cross	DSCSA Implementation in Intra and Inter Healthcare System Medicine Transfers
KitCheck Tim Kress-Spatz	Analyzing gaps and addressing key concerns and testing key concepts relating to the 2023 DSCSA requirements by utilizing and adapting existing commercial methods and technologies
IBM/KPMG/Merck/Walmart Paul Cocuzzo	DSCSA Blockchain interoperability Pilot
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LSPediA Riya Cao	Router Service Solution for Verification/Notification and Interoperability 2023

Participant Panel Q&A

- Please type in your question for the panel into the chat box.
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Break

We will reconvene in 15 minutes.

Open Session

Other Pilot Activities

Speaker	Pilot Project
Center for Supply Chain Studies Robert Celeste	Authorized Trading Partner
LSPediA Michael Ventura	Investigator Pilot (for verification and verification exceptions management)

(NOTE: Some projects involve partnering entities that are not listed in the table.)

Breakout Sessions
Methods for Enhanced
Product Tracing and Verification

Questions to consider:

- **What technologies, methods or systems could enable enhanced product tracing? For example, how to:**
  - Ensure appropriate users have access to the data and system(s)
  - Provide the efficient and accurate exchange of data for each transaction
  - Ensure barcodes can be correctly scanned/read and the data incorporated into transaction documentation or systems
- **What technologies, methods or systems could enable enhanced verification? For example, how to:**
  - Ensure appropriate users have access to the data and system(s)
  - Determine a trading partner is "authorized"
  - Utilize Verification Router Services (VRS) to meet verification requirements related to the product identifier

Breakout Sessions:
Methods for Enhanced Product Tracing

If you received a link to a breakout session:

Breakout Session A	Join now
Breakout Session B	Join in 25 minutes

For other attendees, we will regroup into the main meeting in 55 minutes.

Breakout Sessions
Methods for Enhanced
Product Tracing and Verification

Questions to consider:

- **What technologies, methods or systems could enable enhanced product tracing? For example, how to:**
  - Ensure appropriate users have access to the data and system(s)
  - Provide the efficient and accurate exchange of data for each transaction
  - Ensure barcodes can be correctly scanned/read and the data incorporated into transaction documentation or systems
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  - Ensure appropriate users have access to the data and system(s)
  - Determine a trading partner is “authorized”
  - Utilize Verification Router Services (VRS) to meet verification requirements related to the product identifier

Break

We will reconvene in 10 minutes.

Closing Remarks: Day 1

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

The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security (Day 2)

Virtual Public Meeting

December 8-9, 2020

Opening Remarks: Day 2

Donald Ashley, J.D.
Director of CDER's Office of Compliance

Goals of the Meeting

To further inform FDA's development of the enhanced drug distribution security provisions of the DSCSA

Day 1

- Learn about key findings and lessons learned from participants in FDA's DSCSA Pilot Project Program
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U.S. Food and Drug Administration

Public Meeting: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

Docket No. FDA-2020-N-1862

Wednesday, December 9, 2020: 9:00 am – 4:00 pm

AGENDA

9:00 am	Welcome	Tia Harper-Velazquez, PharmD, JD, MPh *Branch Chief, Supply Chain Strategy & Policy Branch,* *Office of Drug Security, Integrity, and Response (ODSIR), Office of Compliance, CDER*
9:05 am – 9:15 am	Opening Remarks	Donald D. Ashley, JD *Director, Office of Compliance (OC), CDER*
9:15 am – 9:20 am	Goals for Public Meeting and Logistics	Tia Harper-Velazquez
9:20 am – 9:35 am	- Enhanced Drug Distribution Security Requirements and Needs - Enhanced Product Tracing	Abha Kundi, JD, MPH *Regulatory Counsel, ODSIR, OC, CDER*
9:35 am- 10:05 am	Breakout session A: Enhanced Product Tracing	
10:05 am – 10:10 am	**Transition Time**	
10:10 am – 10:40 am	Breakout session B: Enhanced Product Tracing	
10:40 am – 10:55 am	**Break**	
10:55 am – 11:05 am	Facilitate the Gathering	Abha Kundi
11:05 am – 11: 35 am	Breakout session A: Facilitate the Gathering	
11:35 am – 11:40 am	**Transition Time**	
11:40 am – 12:10 pm	Breakout session B: Facilitate the Gathering	
12:10 pm – 1:20 pm	**Lunch Break**	

U.S. Food and Drug Administration

Public Meeting: The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security

Docket No. FDA-2020-N-1862

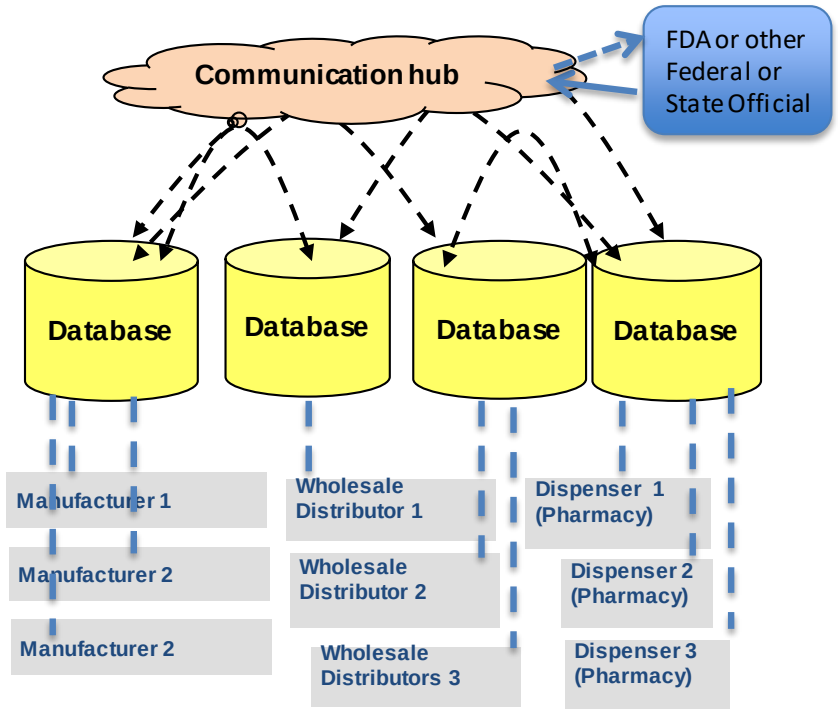
1:20 pm -1:30 pm	Enhanced Verification	Abha Kundi
1:30 pm – 2:00 pm	Breakout session A: Enhanced Verification	
2:00 pm – 2:05 pm	**Transition Time**	
2:05 pm – 2:35 pm	Breakout session B: Enhanced Verification	
2:35 pm -3:00 pm	**Break**	
3:00 pm – 3:10 pm	Recap	Connie Jung
3:10 pm – 3:20 pm	Closing Remarks	Leigh Verbois

Enhanced Drug Distribution Security Requirements and Needs

- Electronic and interoperable
- Secures data & system(s) against falsification, malicious attacks, & breaches
- Ensures protection of confidential commercial information & trade secrets
- Enables authorized trading partners to exchange & store data accurately and efficiently for each transaction
- Enables authorized trading partners to promptly respond to a request for product tracing information
- Enables prompt gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer when appropriately requested
- Enables authorized trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns
- Alerts that a product has been determined to be illegitimate
- Enables scalability for integration by any size business
- Ensures appropriate users have access to the data and system(s)

Enhanced System Architecture - Options

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
- 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
- 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 each databases
- A communications hub connects different databases

For discussion purposes only. Developed for use at this public meeting. This information should not be interpreted as a final decision or position of FDA.

Enhanced Requirements – Product Tracing Information

- In 2023, the electronic transaction information (TI) must include the product identifier at the package level for each package included in the transaction.
- This means the TI will include more information than what is required today.

Breakout Session 1: Enhanced Product Tracing

- How can we ensure appropriate access to the electronic, interoperable system in 2023?
- What steps are you/your sector taking to incorporate product identifier in product tracing information (i.e., transaction information (TI)) as required in 2023?
- How can product tracing be done in 2023 accurately and efficiently:
  - How does inference affect product tracing for the seller? For the buyer?
  - How will trading partners reconcile TI data and product sold or purchased?

Breakout Sessions:
Session 1: Enhanced Product Tracing

If you received a link to a breakout session:

Breakout Session A	Join now
Breakout Session B	Join in 35 minutes

Please select the link in the "participant chat" that corresponds to your previously assigned group number in the email you received for breakout sessions

For other attendees, we will regroup into the main meeting at 10:55 am.

Enhanced Requirements – "Facilitate the Gathering"

For recalls or suspect/illegitimate product investigations, trading partners must have the systems and processes necessary to promptly respond with the transaction information and transaction statement, and to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer upon request by a regulator or authorized trading partner.

Breakout Session 2 : "Facilitate the Gathering"

- How can the technologies and functions of the 2023 system be used to accurately and efficiently "facilitate the gathering" of TI?
  - *What does a request for product tracing information look like? What is the minimum data/info needed in such request? Is this different for each trading partner and FDA?*
  - *What would an information response look like? What is the minimum data/info needed in such response (consider how inference would impact the response)? Is the response different for each trading partner?*
  - *How long should it take for a trading partner to respond to a product tracing information request?*

Breakout Sessions:
Session 2: “Facilitate the Gathering”

If you received a link to a breakout session:

Breakout Session A	Join now
Breakout Session B	Join in 35 minutes

Please select the link in the “participant chat” that corresponds to your previously assigned group number in the email you received for breakout sessions

For other attendees, we will regroup into the main meeting at 1:20 pm.

Lunch Break

We will reconvene at 1:20 pm.

Enhanced Verification

Definition of "verify or verification" [section 581(28) of the FD&C Act]

…determine whether the product identifier affixed to or imprinted upon, a package or homogenous case corresponds to the SNI or lot number and expiration date assigned to the product by the manufacturer or repackager, as applicable…

Why is this important?

- Checks authenticity of product that you have
- Indicates whether the product should be in the supply chain
- Identifies the product identifier associated with an illegitimate product

Breakout Session: Enhanced Verification

- How can verification being done in 2023 to verify product identifiers accurately and efficiently (consider what you have learned from preparation for the verification requirement for saleable returns)?
  - *What does a verification request look like? What is the minimum data/info needed in a verification request? Is this different for each trading partner and FDA?*
  - *What would a verification response look like? What is the minimum data/info needed in a verification response (consider how inference would impact a response)? Is this different for each trading partner?*
  - *How long should it take for a trading partner to respond to a verification request?*

Breakout Session: Enhanced Verification

If you received a link to a breakout session:

Breakout Session A	Join now
Breakout Session B	Join in 35 minutes

Please select the link in the "participant chat" that corresponds to your previously assigned group number in the email you received for breakout sessions

For other attendees, we will regroup into the main meeting at 3:00 pm.

Break

We will reconvene in 25 minutes

Recap - Day 1
DSCSA Pilot Projects and Other Pilot Activities

What technologies, methods or systems could enable enhanced product tracing or verification?

- Credentialing for determining authorized trading partner
- Ensuring barcode quality for data capture and exchange
- Potential support of RFID tags as a data carrier
- Use of centralized, de-centralized systems, or combination (semi-centralized) systems
- Use of Verification Router Services (VRS) for verification request, however not all trading partners are currently adopting this method

Recap – Day 2
Enhanced Product Tracing (1)

- **How can we ensure appropriate access to the electronic, interoperable system in 2023?**
  - Confirming authorized trading partners status before they gain access, possibly from one source/body
  - Keeping data centralized vs. de-centralized
  - Need for education of small entities
- **What steps are you/your sector taking to incorporate product identifier in product tracing information (i.e., transaction information (TI)) as required in 2023?**
  - Many manufacturers using EPCIS to incorporate product identifier data into TI
  - Some trading partners are using ASN (advance ship notices)
  - Data integrity issues causing errors
  - Need for education of small entities

Recap – Day 2
Enhanced Product Tracing (2)

- **How can product tracing be done in 2023 accurately and efficiently:**
  - **How does inference affect product tracing for the seller? For the buyer?**
  - **How will trading partners reconcile TI data and product sold or purchased?**

    - Aggregation is essential operationally for shipping homogenous cases and pallets
    - Inference is also essential operationally, but inference would stop once a homogenous case or pallet is broken/opened
    - Are there technologies to help trading partners to not have to individually scan?
    - Scanning the 2D data matrix barcode is more likely on the outbound (i.e., when packing an order or shipment) rather than inbound (i.e., when receiving an order or shipment)

Recap – Day 2
Enhanced Product Tracing (3)

How can the technologies and functions of the 2023 system be used to accurately and efficiently "facilitate the gathering" of TI?

- **What does a request for product tracing information look like? What is the minimum data/info needed in such request? Is this different for each trading partner and FDA?**
- **What would an information response look like? What is the minimum data/info needed in such response (consider how inference would impact the response)? Is the response different for each trading partner?**
- **How long should it take for a trading partner to respond to a product tracing information request?**

- Requests may look different (i.e., for a single product identifier or recall of an entire lot)
- Response may look different based on the request (only give data that is requested)
- Response time may depend on the volume of data needed for the response
- For recalls, frequency of type of requests dictates amount of data provided and value is not certain

Recap – Day 2
Enhanced Verification

How can verification be done in 2023 to verify product identifiers accurately and efficiently (consider what you have learned from preparation for the verification requirement for saleable returns)?

- **What does a verification request look like? What is the minimum data/info needed in a verification request? Is this different for each trading partner and FDA?**
- **What would a verification response look like? What is the minimum data/info needed in a verification response (consider how inference would impact a response)? Is this different for each trading partner?**
- **How long should it take for a trading partner to respond to a verification request?**

- Some may not rely on VRS in 2023 and self-verify
- Manual verification may need to be maintained (e.g., by telephone or email)
- VRS is being used for saleable returns and can be use for 2023 requirements
- Communications need to be standardized across the supply chain
- Time-sensitive response to verification requests is essential for investigations

Closing Remarks: Day 2

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

How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov
- Submit written comments to:
  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 **FDA-2020-N-1862**.
- Please note that the deadlines for submitting either electronic or written comments is **December 28, 2020**.
- Stakeholder input essential and valued!

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 project programs):

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