Drug Supply Chain Security Act (DSCSA)
Public Meeting Series

Enhanced Drug Distribution Security

Meeting 1

August 23, 2017

White Oak Campus

Silver Spring, MD

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
August 23, 2017

Agenda

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:10 am	Welcome and Opening Remarks	Donald Ashley
9:10 – 9:20 am	Goals of the Public Meeting	Dan Bellingham
9:20 – 9:30 am	FDA's Vision for 2023	Ilisa Bernstein
9:30 – 10:25am	Stakeholders' Vision for 2023	Invited Speakers
10:25 – 10:40am	Break	
10:40 – 12:00 pm	Breakout and group discussions	
12:00 – 1:00 pm	Lunch	
1:00 – 1:10 pm	Enhanced Drug Distribution Security Needs	Connie Jung
1:10 – 2:30 pm	Breakout and group discussions	
2:30 – 2:45 pm	Break	
2:45 – 3:15 pm	Group discussions (continued)	
3:15 – 3:45 pm	Group Discussion: Path Forward for Collaboration	Ilisa Bernstein
3:45 – 4:00 pm	Closing Remarks	Dan Bellingham
4:00 pm	Adjourn	

Goals of the Meeting

- This is the first in a series of three public meetings that will provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss with FDA, and provide input on, strategies and issues related to the enhanced drug distribution security provisions of the DSCSA.
- FDA would like to obtain information and input from attendees about issues related to:
  - the vision for 2023
  - the enhanced drug distribution security needs related to tracing prescription drugs at the package level
- The information gathered from the meeting and the public comments submitted to the docket will further inform FDA's development of the enhanced drug distribution security provisions of the DSCSA.

How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2017-N-3857.
- Please note that the deadlines for submitting either electronic or written comments are 30 days after the meeting to which the comments relate.

For Meeting #1, comments are due by September 22, 2017

- Stakeholder input essential and valued!

Meeting Logistics

- Housekeeping (pre-order lunch, restrooms)
- Participants have been assigned to specific tables to ensure representation of different trading partner and stakeholder groups.
- Break Sessions:
  - Sessions 1 and 2 will involve break outs/small group discussions.
  - Each small group will involve 2 tables working together to discuss ideas that will inform the development of the enhanced drug distribution security system.
  - Each group will have FDA representatives as a facilitator and a scribe to aid the discussion and capture participant input.
- Information captured will be aggregated and not associated with a specific individual or company.
- Press/Media representative(s) may be in attendance and have a separate assigned table.
- The Concepts and Terminology document is provided to help facilitate discussions at these public meetings and should not be interpreted as legal or regulatory definitions or guidance.

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Vision of the 2023 for the Drug Distribution System

- Provide increased public health benefits
- Ensure diligence and vigilance by all trading partners
- Support FDA's compliance and enforcement efforts
- Be adaptable and flexible
- Be interoperable with the health care system and global marketplace

Stakeholders' Vision for 2023

BIO	Victoria Dohnal
AAM	Mark Hendrickson
HDA	Anita Ducca
NACDS	Christopher Smith
APhA	Jenna Ventresca

Breakout Session #1
Discussion Questions
Vision for 2023

1. How will the 2023 system and processes protect and enhance public health?
2. In what ways can the system and processes be used to prevent, detect, and respond to suspect and illegitimate products?
3. What are the roles of manufacturers, wholesalers, repackagers, dispensers, FDA, and others in the 2023 systems and processes?
4. Are there opportunities for interoperability of the 2023 system that can be leveraged within the health care system? What are the benefits and the risks?
5. Where does the 2023 system and processes fit within the global supply chain/marketplace?

Breakout Session #1
Discussion Questions
Vision for 2023

	Breakout Discussions
1. How will the 2023 system and processes protect and enhance public health?	– **All Groups**
2. In what ways can the system and processes be used to prevent, detect, and respond to suspect and illegitimate products?	– **Group 1 (Tables 1 & 2)** **Group 2 (Tables 3 & 4)**
3. What are the roles of manufacturers, wholesalers, repackagers, dispensers, FDA, and others in the 2023 systems and processes?	– **Group 3 (Tables 5 & 6)** **Group 4 (Tables 7 & 8)**
4. Are there opportunities for interoperability of the 2023 system that can be leveraged within the health care system? What are the benefits and the risks?	– **Group 5 (Tables 9 & 10)** **Group 6 (Tables 11 & 12)**
5. Where does the 2023 system and processes fit within the global supply chain/marketplace?	– **Group 7 (Tables 13 & 14)** **Group 8 (Tables 15 & 16)**

Enhanced Drug Distribution Needs

- Think about our discussion about the vision
- What do we need for enhanced drug distribution?
- What are the functionalities/properties are needed?

Enhanced Drug Distribution Goals

The DSCSA establishes requirements for the interoperable, electronic tracing of products at the package level that go into effect in November 2023. The 2023 system is expected to provide:

- Electronic exchange of information by trading partners at the package level
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products when found
- Improved efficiency of recalls
- Transparency and accountability in the drug supply chain

Breakout Session #2 – Discussion
Enhanced Drug Distribution Needs
Proposed Functionalities or Properties

- Provides appropriate access to data necessary for interoperability
- Secures data and systems against falsification, malicious attacks, and breaches
- Enables integration of any size businesses
- Fully electronic and interoperable
- Enables trading partners and Federal/State officials to access and use data in the system, as appropriate
- Enables trading partners to capture, maintain, and exchange data accurately and efficiently
- Enables trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns
- Verifies that a trading partner is an "authorized" trading partner
- Improves the ability of FDA and trading partners to prevent distribution of suspect or illegitimate product
- Captures the product identifier of a product for each transaction
- Provides the status of a product through the use of the product identifier (e.g., "dispensed" or "expired")
- Creates the distribution history of the product

Breakout Session #2
Discussion Questions
Enhanced Drug Distribution Needs

- **What do we need to do to improve the efficiency of the supply chain ?**
  (*e.g., improvements related to product distribution, exchange of data, communications, and notification)*

- **What do we need to do to increase the security of the drug distribution supply chain ?**
  (e.g., improve efforts regarding verification products and authorized trading partners, prevention of the distribution of illegitimate product, investigation of suspect and illegitimate product, initiation and termination of notifications)

- **What do we need to do to ensure the security of the 2023 system?**
  (e.g., data security, authorized access)

Group Discussion
Path Forward for Collaboration

Partnership is essential

- **What other efforts are underway to build some or all of the 2023 system?**
- **What opportunities are there for leveraging?**
- **What else is needed?**
- **Path forward…**

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Next DSCSA Public Meetings

Date(s)	Topics	Advance Registration
December 5-6, 2017	• Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference	October 2-27, 2017
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system	January 2-26, 2018