Drug Supply Chain Security Act (DSCSA)
Public Meeting Series

Enhanced Drug Distribution Security

December 5-6, 2017

White Oak Campus

Silver Spring, MD

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
December 5-6, 2017

Agenda
Day 2: December 6, 2017

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Opening Remarks	Ilisa Bernstein FDA/CDER
9:15 – 9:45 am	A Safer Europe Without Falsified Medicines	Lorenzo Terzi Delegation of the European Union to the United States of America
9:45 – 10:15 am	Aggregation and Inference	Abha Kundi FDA/CDER
	Aggregation: Principles, Challenges and Solutions	Adriano Fusco OPEN-SCS
	Inference – Overview	FDA
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Aggregation and Inference (continued) • *Supply Chain Sector Breakout Sessions* • *Large Group Discussion*	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	2023 Scenario Exercises • *Breakout Sessions* • *Large Group Discussion*	Eleni Anagnostiadis FDA/CDER
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	Large Group Discussion (continued)	
3:45 – 4:00 pm	Closing Remarks	Ilisa Bernstein FDA/CDER
4:00 pm	Adjourn	

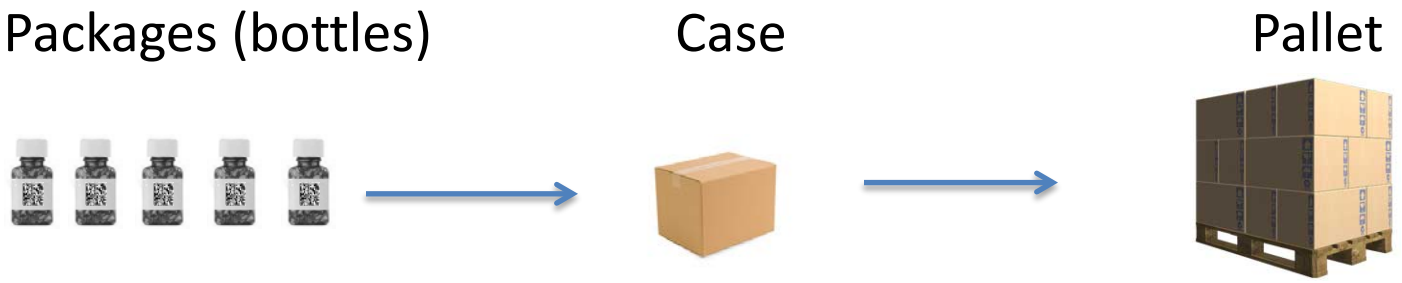
EU Experience

Speaker:

- Lorenzo Terzi, Minister Counselor, Health and Food Safety, Delegation of the European Union to the United States of America

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.

Aggregation

Speaker:

– Adriano Fusco, OPEN-SCS

Inference

We've heard that:

- Inference applies when:
  - a group of products moves through the supply chain in a shipping container (e.g., pallets, totes, etc.), and
  - recipients do not read each product identifier on each product in the container; instead,
  - recipients check the identifier on the shipping container and the associated aggregated information provided by the upstream trading partner.
  - If the information corresponds, the identity of the products inside the shipping container can be inferred.
- In such circumstances, inference allows the recipient to leave the container intact, which may facilitate certain efficiencies, cost-savings and potentially safety.

Breakout Session
Aggregation and Inference

- What is your sector's need for aggregation and inference? Does your sector currently use some of these practices as part of your normal operations?
- What are the advantages and disadvantages of the use of aggregation and inference?
- What procedures are essential for aggregation and/or inference?
- When would inference be used in distribution? Is it essential for every trading partner?
- Would the use of aggregation and inference change when the DSCSA's enhanced drug distribution security provisions take effect in 2023? What would the implementation challenges be at that stage?

Breakout Session

Aggregation and Inference

Group	Room	Sector
A	Great Room	Manufacturers
B	Room 1406	Wholesale Distributors
C	Room 1408	Dispensers/Pharmacy

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
December 5-6, 2017

Agenda
Day 2: December 6, 2017

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Opening Remarks	Ilisa Bernstein FDA/CDER
9:15 – 9:45 am	A Safer Europe Without Falsified Medicines	Lorenzo Terzi Delegation of the European Union to the United States of America
9:45 – 10:15 am	Aggregation and Inference	Abha Kundi FDA/CDER
	Aggregation: Principles, Challenges and Solutions	Adriano Fusco OPEN-SCS
	Inference – Overview	FDA
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Aggregation and Inference (continued) • *Supply Chain Sector Breakout Sessions* • *Large Group Discussion*	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	2023 Scenario Exercises • *Breakout Sessions* • *Large Group Discussion*	Eleni Anagnostiadis FDA/CDER
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	Large Group Discussion (continued)	
3:45 – 4:00 pm	Closing Remarks	Ilisa Bernstein FDA/CDER
4:00 pm	Adjourn	

Breakout Session
2023 Scenarios

When analyzing the scenarios below please consider:

- How will these scenarios likely be handled by the pharmaceutical distribution supply chain in 2023, now that product will be serialized?
- Identify and state any assumptions you have about how the process would work.
- Explain what steps are essential to meeting DSCSA requirements in addressing these scenarios and how you propose these steps be conducted?
- What standards are needed to enable a system used by trading partners to accomplish these steps?
- What should the roles of trading partners and other supply chain stakeholders be in 2023?
- What technical or operational issues can be worked out amongst trading partners through business decisions or relationships?
- What do stakeholders need from FDA (requirements, guidance, or other info)?

Breakout Session
Scenario Exercises

Group1	Breakout Session in:	
Groups 1 & 2	Great Room	Scenario # 1
Groups 3 & 4	Great Room	Scenario # 2
Group 5	Room 1406	Scenario # 3
Group 6	Room 1408	Scenario # 4

Breakout Session
Scenario # 1

1. A Manufacturer is investigating a suspect or illegitimate product. The Manufacturer discovered this product through a verification request from a dispenser.

a) How will the Manufacturer share information with trading partners for verification and product tracing at the package-level? How will the Manufacturer share information with FDA for verification and product tracing at the package-level?

b) How do you envision the process by which an investigation will be conducted? Will you coordinate your investigation with other trading partners? How will you manage quarantine and investigation? Are these steps different from current practices?

c) If the Manufacturer determines that the product is "cleared", how do you envision this information be incorporated into the enhanced system in 2023 so that the product may be further distributed?

[CONTINUTED ON NEXT SLIDE]

Breakout Session
Scenario # 1

1. A Manufacturer is investigating a suspect or illegitimate product. The Manufacturer discovered this product through a verification request from a dispenser. [CONTINUED]

d) If the product is determined to be illegitimate, how do you envision this information to be incorporated into the enhanced system in 2023 so the product will not be further distributed?

e) How would you manage a recall? How will the enhanced system aid in the recall process to ensure the products are removed from distribution? (e.g., will the electronic interoperable system provide you with the names of all trading partners who have the product in their inventory?)

Breakout Session
Scenario # 2

2. You have purchased product and have not used inference when you received your order. You discover that there is an error in the order whereby you have received product tracing information for a package of product that is missing from the order.

a) How would this error be resolved using the electronic interoperable system of 2023? You are the purchaser, what do you do? You are the seller, what do you do once you have been notified of the error by your trading partner?

b) If you had used inference when you received order, would this error be found?

- If so, how or when if you are a wholesale distributor? If so, how or when if you are a dispenser?
- If not, what is needed so that the error would be found? (i.e., new or different processes, changes to the system, other ?)

Breakout Session
Scenario # 3

3. A dispenser is returning a product that it believes is a saleable return that it purchased from one of its wholesale distributors.

a) How is the return product handled and processed to determine it is a saleable return and acceptable for distribution?

b) If the dispenser is returning product that it believes is a saleable return that it purchased directly from the manufacturer, is the process for determining whether it is a saleable return and acceptable for distribution different from a)?

Breakout Session
Scenario # 4

4. A Wholesale Distributor's truck was stolen with serialized product from different manufacturers. The product identifiers of the stolen product are known. The Wholesale Distributor notifies FDA.

   a) How should this information be conveyed to the pharmaceutical supply chain?

   b) After this event, how will trading partners know if they purchased the stolen product?

   c) What elements of data architecture should be in place to ensure that these stolen products don't get back into the supply chain and dispensed to patients?

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.
- Stakeholder input essential and valued!

Next DSCSA Public Meeting

Date(s)	Topics	Advance Registration
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system	January 2-26, 2018