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	Goal 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**	

** Minor adjustments may be made*

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

(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 – 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*

** Minor adjustments may be made*

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

(Day 2 – Continued)

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	

** Minor adjustments may be made*