

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 <i>Senior Advisor for Policy, Office of Drug Security, Integrity, and Response (ODSIR), Office of Compliance (OC), Center for Drug Evaluation and Research (CDER)</i>
9:05 am – 9:15 am	Opening Remarks	Patrizia Cavazzoni, MD <i>Acting Center Director, CDER</i>
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 <i>Policy Analyst, ODSIR, OC, CDER</i>
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

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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 <i>Director, Office of Drug Security, Integrity, and Response, OC, CDER</i>

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

AGENDA

9:00 am	Welcome	Tia Harper-Velazquez, PharmD, JD, MPH <i>Branch Chief, Supply Chain Strategy & Policy Branch, Office of Drug Security, Integrity, and Response (ODSIR), Office of Compliance, CDER</i>
9:05 am – 9:15 am	Opening Remarks	Donald D. Ashley, JD <i>Director, Office of Compliance (OC), CDER</i>
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 <i>Regulatory Counsel, ODSIR, OC, CDER</i>
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	

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