

U.S. Food and Drug Administration
Public Meeting: Enhanced Drug Distribution Security at the Package Level Under
the Drug Supply Chain Security Act (DSCSA)

Docket No. FDA-2021-N-1004

Tuesday, November 16, 2021: 9:00 am – 4:00 pm EST

AGENDA

9:00 am	Welcome	Daniel Bellingham <i>Policy Analyst, Office of Drug Security, Integrity and Response (ODSIR), CDER/OC/FDA</i>
9:00 am – 9:05 am	Opening Remarks	Donald D. Ashley, J.D. <i>Director, Office of Compliance, CDER/FDA</i>
9:05 am – 9:10 am	Goals of the Public Meeting and Logistics	Daniel Bellingham
9:10 am – 9:35 am	Overview of Enhanced Drug Distribution Security	Abha Kundi, J.D., M.P.H. <i>Regulatory Counsel, ODSIR, CDER/OC/FDA</i>
<i>Stakeholder Presentations</i>		
9:40 am -9:50 am	Pharmaceutical Distribution Security Alliance (PDSA)	Mark Hendrickson
9:50 am – 10:00 am	Partnership for DSCSA Governance, Inc. (PDG)	Eric Marshall
10:00 am – 10:10 am	Pharmaceutical Research and Manufacturers of America (PhRMA)	Ryan Kaat

10:10 am – 10:20 am	Novartis	Dave Mason
10:20 am – 10:30 am	FDA Questions to Speakers	
10:30 am -10:50 am	Break	
10:50 am – 11:00 am	Healthcare Distribution Alliance (HDA)	Anita Ducca
11:00 am – 11:10 am	Cardinal Health	Maryann Nelson
11:10 am – 11:20 am	McKesson	Scott Mooney
11:20 am – 11:30 am	Smith Drug Company	Brad Pine
11:30 am – 11:40 am	FDA Questions to Speakers	
11:40 am – 12:40 pm	Break	
12:40 pm – 12:50 pm	American Pharmacists Association (APhA)	Ilisa Bernstein
12:50 pm – 1:00 pm	Walgreens	Michele Davidson
1:00 pm – 1:10 pm	FDA Questions to Speakers	
1:10 pm – 1:50 pm	Break	
1:50 pm – 2:00 pm	National Association of Boards of Pharmacy (NABP)	Josh Bolin
2:00 pm – 2:10 pm	Softgroup	Iordan Dunkov
2:10 pm – 2:20 pm	LSPEdia	Riya Cao
2:20 pm- 2:30 pm	FDA Questions to Speakers	
2:30 pm – 3:00 pm	Break	
3:00 pm – 3:45 pm	<i>Open Comments Session</i>	Moderator: Daniel Bellingham
3:45 pm – 3:55 pm	FDA Questions to Speakers	
3:55 pm – 4:00 pm	Closing Remarks	Leigh Verbois, PhD



*Director, Office of Drug
Security, Integrity, and
Response, CDER/OC/FDA*