

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), FDA</i>
9:00 am – 9:05 am	Opening Remarks	Donald D. Ashley, J.D. <i>Director, Office of Compliance, 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 the Enhanced Drug Distribution Security Requirements	Abha Kundi, J.D. <i>Regulatory Counsel, ODSIR, FDA</i>
9:40 am -10:20 am	<i>Stakeholder Presentations: Session 1</i>	
10:20 am -10:50 am	Break	
10:50 am – 11:40 am	<i>Stakeholder Presentations: Session 2</i>	
11:40 am – 12:40 pm	Lunch	
12:40 pm – 1:20 pm	<i>Stakeholder Presentations: Session 3</i>	

1:20 pm – 1:50 pm

Break

1:50 pm – 2:30 pm

*Stakeholder Presentations:
Session 4*

2:30 pm – 3:00 pm

Break

3:00 pm – 3:45 pm

Open Comments Session

3:45 pm – 4:00 pm

Closing Remarks

Leigh Verbois

Director; ODSIR; FDA