FOOD AND DRUG ADMINISTRATION (FDA)

Packaging, Storage, and Disposal Options to Enhance Opioid Safety
Exploring the Path Forward

Sheraton Silver Spring
8777 Georgia Ave., Silver Spring, MD 20910

December 11 and 12, 2017

AGENDA
Meeting Website: https://www.fda.gov/Drugs/NewsEvents/ucm571797.htm
Docket No. FDA-2017-N-5897

Monday, December 11, 2017		
7:30 a.m.	Registration	
8:30 am	Welcome, Overview, Introductions	Irene Z. Chan, PharmD CDR, U.S. Public Health Service Deputy Director Division of Medication Error Prevention and Analysis (DMEPA), CDER, FDA
8:45 am	Opening Remarks	Scott Gottlieb, MD Commissioner FDA
8:55 am	Session 1: Presentation Packaging, Storage, and Disposal Options to Enhance Opioid Safety: Target Problems and Labeling Considerations	Irene Z. Chan, PharmD
9:10 am	Panel Discussion	Moderators: Irene Z. Chan, PharmD Iris Masucci, PharmD Special Assistant for Labeling Office of Medical Policy CDER, FDA
10:10 am	Audience Participation	Moderator: Irene Z. Chan, PharmD
10:30 am	Break	

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10:45 am	Session 2: Presentation Design Considerations for Packaging, Storage, and Disposal Options to Enhance Opioid Safety	Gary Slatko, MD Associate Director Office of Medication Error Prevention and Risk Management (OMEPRM), CDER, FDA
11:00 am	Panel Discussion	Moderators: Gary Slatko, MD Irene Z. Chan, PharmD
12:00 pm	Audience Participation	Moderator: Gary Slatko, MD
12:30 pm	Lunch (on your own)	
1:30 pm	Session 3: Presentation Regulatory Considerations for Packaging, Storage, and Disposal Options to Enhance Opioid Safety	Patrick Raulerson, JD Regulatory Counsel Office of Regulatory Policy CDER, FDA
1:45 pm	Panel Discussion	Moderators: Patrick Raulerson, JD James Bertram, PhD Product Jurisdictional Officer Office of Device Evaluation CDRH, FDA
2:30 pm	Audience Participation	Moderator: Patrick Raulerson, JD
2:45 pm	Break	
3:00 pm	Session 4: Presentation Integrating Packaging, Storage, and Disposal Options into the Medication Use System	Kayla Cierniak, PharmD ORISE Fellow Division of Medication Error Prevention and Analysis (DMEPA), CDER, FDA

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3:15 pm	Panel Discussion	Moderator: Irene Z. Chan, PharmD Sharon Hertz, MD Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), CDER, FDA
4:15 pm	Audience Participation	Moderator: Sharon Hertz, MD
4:45 pm	Summary and closing remarks for Day 1	Irene Z. Chan, PharmD
5:00 pm	Adjournment	
Tuesday, December 12, 2017		
7:30 am	Registration	
8:30 am	Welcome back, Overview	Irene Z. Chan, PharmD
8:35 am	Opening Remarks	Doug Throckmorton, MD Deputy Director for Regulatory Programs CDER, FDA
8:45 am	Presentation 1 Premarket Data and Labeling Considerations for Packaging, Storage, and Disposal Options to Enhance Opioid Safety	Irene Z. Chan, PharmD
9:00 am	Presentation 2 Challenges and Data Needs in Assessing the Impact of Packaging, Storage, and Disposal Options After an Opioid Drug Product is Marketed	Tamra Meyer, PhD, MPH Epidemiologist Division of Epidemiology II CDER, FDA

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9:15 am	Session 5: Presentation 1 Poison Prevention, Product Safety and Development: Preventing Unintentional Exposures	Laura Bix, PhD Associate Director Michigan State University School of Packaging
9:25 am	Session 5: Presentation 2 Unsupervised Ingestions by Young Children: Monitoring Emergency Department Visits for Opioid Overdoses	Daniel S. Budnitz, MD, MPH CAPT, U.S. Public Health Service Director Medication Safety Program Division of Healthcare Quality Promotion CDC
9:35 am	Session 5: Panel Discussion Accidental Exposure – Pre and Post Market Data and Labeling Considerations	Moderators: Richard (Rik) Lostritto, PhD Associate Director for Science Office of Policy for Pharmaceutical Quality (OPPQ), CDER, FDA Judy Staffa, PhD, RPh Associate Director for Public Health Initiatives, Office of Surveillance & Epidemiology CDER, FDA
10:30 am	Audience Participation	Moderator: Judy Staffa, PhD, RPh
10:45 am	Break	
11:00 am	Session 6: Presentation 1 Improving Medication Adherence Through Innovative Packaging	Walter Berghahn Executive Director, Healthcare Compliance Packaging Council (HCPC)
11:20 am	Session 6: Panel Discussion Misuse - Pre and Post Market Data and Labeling Considerations	Moderator: Tamra Meyer, PhD, MPH Kathryn Aikin, PhD Senior Social Science Analyst, Research Team Lead, Office of Prescription Drug Promotion Office of Medical Policy CDER/FDA

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12:30 pm	Lunch (on your own)	
1:30 pm	Audience Participation	
2:00 pm	Session 7: Presentation 1 Pre-Market Abuse Liability Studies – Parallels for Studying Third Party Access Impacted by Packaging, Storage, and Disposal Options	Dominic Chiapperino, PhD Acting Director Controlled Substance Staff CDER/FDA
2:10 pm	Session 7: Panel Discussion Third Party Access - Pre and Post Market Data and Labeling Considerations	Moderator: Dominic Chiapperino, PhD Kathryn Aikin, PhD
3:15 pm	Audience Participation	Moderator: Kathryn Aikin, PhD
3:30 pm	Break	
3:45 pm	Session 8: Panel Discussion Excess Supply - Pre and Post Market Data and Labeling Considerations	Moderator: Sharon Hertz, MD Tamra Meyer, PhD, MPH
4:30 pm	Audience Participation	Moderators: Tamra Meyer, PhD, MPH
4:45 pm	Closing Remarks	Irene Z. Chan, PharmD Doug Throckmorton, MD
5:00 pm	Adjournment	