FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities

Sheraton Silver Spring Hotel
8777 Georgia Avenue, Silver Spring, Maryland 20910

July 10-11, 2017

AGENDA
Meeting Website: https://www.fda.gov/Drugs/NewsEvents/ucm540845.htm
Docket No. FDA-2017-N-2903

Day 1		
8:30 am	Welcome/Introductions	Judy Staffa, PhD, RPh Associate Director for Public Health Initiatives Office of Surveillance & Epidemiology CDER, FDA
8:35 am	Opening Remarks	Scott Gottlieb MD Commissioner FDA
8:45 am	**Presentation:** Overview of Public Meeting & Day 1 Roadmap	Judy Staffa, PhD, RPh
9:15 am	**Session 1: Presentation** Current Data Resources Used to Investigate Drug Products with Properties Intended to Deter Abuse	Cynthia Kornegay, PhD Lead, Prescription Drug Abuse Team Division of Epidemiology II Office of Surveillance & Epidemiology CDER, FDA
9:30 am	Panel Discussion	Moderators: Cynthia Kornegay, PhD Hana Lee, PhD Visiting Associate Division of Biometrics VII Office of Biostatistics CDER, FDA
10:30 am	Audience Participation	Moderator: Hana Lee, PhD
10:45 am	Break	
11:00 am	**Session 2: Presentation** Sampling, Metrics, and Denominators	Kunthel By, PhD Mathematical Statistician Division of Biometrics VII Office of Biostatistics CDER, FDA

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11:15 am	Panel Discussion	Moderators: Kunthel By, PhD Tamra Meyer, PhD, MPH Epidemiologist Division of Epidemiology II Office of Surveillance and Epidemiology CDER, FDA
12:15 pm	Audience Participation	Moderator: Tamra Meyer, PhD, MPH
12:30 pm	Lunch (on your own)	
1:30 pm	**Session 3: Presentation** Causal Inference and Control for Confounding	Jana McAninch, MD, MPH, MS Medical Officer/Epidemiologist Division of Epidemiology II Office of Surveillance and Epidemiology CDER, FDA
1:45 pm	Panel Discussion	Moderators: Jana McAninch, MD, MPH, MS Diqiong (Joan) Xie, PhD Mathematical Statistician Division of Biometrics VII Office of Biostatistics CDER, FDA
2:45 pm	Audience Participation	Moderator: Diqiong (Joan) Xie, PhD
3:00 pm	Break	
3:15 pm	**Session 4: Summary** Strategies to overcome/mitigate some of the identified challenges	Judy Staffa, PhD, RPh Mark Levenson, PhD Director Division of Biometrics VII Office of Biostatistics CDER, FDA

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3:30 pm	Panel Discussion	Moderators: Judy Staffa, PhD, RPh Mark Levenson, PhD.
4:30 pm	Audience Participation	Moderator: Judy Staffa, PhD, RPh
4:45 pm	Summary and closing remarks for Day 1	Judy Staffa, PhD, RPh
5:00 pm	Adjourn	
Day 2		
8:30 am *5 min*	Welcome back	Mark Levenson, PhD
8:35 am	Opening Remarks	Doug C. Throckmorton, MD Deputy Director for Regulatory Programs Office of the Center Director CDER, FDA
8:45 am	**Presentation:** Day 2 Roadmap	Mark Levenson, PhD
9:05 am	**Session 5: Presentation** Building on Established National Surveys	Jana McAninch, MD, MPH, MS
9:20 am	Panel Discussion	Moderators: Jana McAninch, MD, MPH, MS Diqiong (Joan) Xie, PhD
10:20 am	Break	
10:35 pm	Panel Discussion (Cont.)	
10:55 am	Audience Participation	Moderator : Diqiong (Joan) Xie, PhD
11:15 am	**Session 6: Presentation** Designs That Assess Exposure and Outcome in the Same Individuals Over Time	Tamra Meyer, PhD, MPH
11:30 am	Panel Discussion	Moderators: Tamra Meyer, PhD, MPH Hana Lee, PhD

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12:30 pm	Lunch (on your own)	
1:30 pm	Audience Participation	Moderator: Hana Lee, PhD
1:45 pm	**Session 7: Presentation** Leveraging other data: Linking and benchmarking	Cynthia Kornegay, PhD
2:00 pm	Panel Discussion	Moderators: Cynthia Kornegay, PhD Kunthel By, PhD
3:00 pm	Audience Participation	Moderator: Kunthel By, PhD
3:15 pm	Break	
3:30 pm	**Session 8:** Next Steps	Judy Staffa, PhD, RPh Mark Levenson, PhD
3:45 pm	Panel Discussion	Moderators: Judy Staffa, PhD, RPh Mark Levenson, PhD
4:30 pm	Audience Participation	Moderator: Mark Levenson
4:45 pm	Closing remarks	Mark Levenson, PhD Judy Staffa, PhD, RPh Doug Throckmorton, MD
5:00 pm	Adjourn	