

2017 Intergovernmental Working Meeting on Pharmacy Compounding

U.S. Food and Drug Administration
White Oak Campus, Great Room
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

AGENDA

Tuesday, September 26, 2017

8:00 AM – 5:15 PM

- 8:00 AM – 9:00 AM** **Registration and Informal Networking**
- 9:00 AM – 9:30 AM** **Welcome and Introduction**
- Nick Alexander, JD, Acting Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation, and Analysis (OPPLA), FDA
 - Anna Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, OPPLA/FDA
 - Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Center for Drug Evaluation and Research (CDER); Agency Lead for Compounding, FDA
- 9:30 AM – 10:15 AM** **Compounding Regulatory Policy Update**
- Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Agency Lead for Compounding, CDER/FDA
 - Sara Rothman, MPH, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- 10:15 AM – 10:30 AM** **Break**
- 10:30 AM – 11:15 AM** **FDA Incidents, Inspections and Enforcement Update**
- Ellen Morrison, Assistant Commissioner for Operations, Office of Regulatory Affairs (ORA), FDA
 - Michael Levy, JD, Deputy Director for Policy and Analysis, Office of Compliance, CDER/FDA
- 11:15 AM – 12:15 PM** **Balancing Federal and State Oversight**
- Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Agency Lead for Compounding, CDER/FDA
 - Ruey Ju, PharmD, JD, Senior Advisor for Compounding Compliance and Enforcement, CDER/FDA
 - Virginia Herold, MS, Executive Officer, California State Board of Pharmacy
 - Anthony Rubinaccio, RPh, Executive Director, New Jersey Board of Pharmacy

12:15 PM – 1:30 PM

Lunch

1:30 PM – 2:15 PM

Balancing Federal and State Oversight – Breakout Sessions

2:15 PM – 3:30 PM

Outsourcing Facility Oversight

- Gabrielle Cosel, MS, Policy Analyst, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Sara Rothman, MPH, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Kimberly Leonard, Executive Secretary; Pharmacy Supervisor, Practice and Registration, New York State Board of Pharmacy
- Karen Tannert, RPh, MPH, Chief Pharmacist, Consumer Protection Division, Drugs and Medical Devices Group, Texas Department of State Health Services

3:30 PM – 3:45 PM

Break

3:45 PM – 5:00 PM

Animal Drug Compounding

- Eric Nelson, Director, Division of Compliance, Center for Veterinary Medicine (CVM)/FDA
- Patrice Brooks-Gelling, JD, MPH, Regulatory Counsel, Office of Surveillance and Compliance, Center for Veterinary Medicine CVM/ FDA
- Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Agency Lead for Compounding, CDER/FDA
- Mark Hardy, PharmD, Executive Director, North Dakota Board of Pharmacy

5:00 PM – 5:15 PM

Closing Remarks

8:00 AM – 8:45 AM Registration and Informal Networking

8:45* AM – 9:00 AM Opening Remarks

***Note earlier start time**

- Nick Alexander, JD, Acting Director of Intergovernmental Affairs, OPPLA/FDA
- Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Agency Lead for Compounding, CDER/FDA

9:00 AM – 10:00 AM Compounding Special Issues

- Gail Bormel, JD, RPh, Director, Division of Prescription Drugs, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Kari Shanard-Koenders, RPh, Executive Director, South Dakota Board of Pharmacy
- Ruey Ju, PharmD, JD, Senior Advisor for Compounding Compliance and Enforcement, CDER/FDA
- Steve Hart, RPh, Executive Director, Kentucky Board of Pharmacy
- Sara Rothman, MPH, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA

10:00 AM – 10:15 AM Break

10:15 AM – 12:30 PM Compounding Special Issues – Breakout Sessions

12:30 PM – 1:45 PM Lunch

1:45 PM – 3:00 PM Information Sharing and Technical Assistance

- Kathleen Anderson, PharmD, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA
- José Martinez, Jr., Supervisory Consumer Safety Officer, Office of Pharmaceutical Quality Operations, ORA/FDA
- Lauren DiPaola, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA
- Susan Alverson, PharmD, Executive Secretary, Alabama Board of Pharmacy
- Beth Ferguson, PharmD, Deputy Director, Minnesota Board of Pharmacy

3:00 PM – 3:45 PM Open Forum – Tabletop Discussions

3:45 PM – 5:15 PM Sneak Peek: FDA Educational Session for Compliance Officers

- Russell Fortney, RPh, Branch Chief, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Ian Deveau, PhD, Branch Chief, Office of Manufacturing Quality, Office of Compliance, CDER/FDA
- Susan Laska, MS, Senior Advisor Medical Products, ORA/FDA

5:15 PM – 5:30 PM Closing Remarks