2016 Inter-governmental 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 20, 2016 **8:00 AM – 4:30 PM**

8:00 AM – 9:00 AM **Registration**

9:00 AM – 9:15 AM **Welcome and Introduction**
Brian Kehoe, Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation and Analysis, FDA

Julie Dohm, Senior Science Advisor for Compounding, Center for Drug Evaluation and Research (CDER); Agency Lead for Compounding, FDA

9:15 AM – 10:30 AM **Compounding Regulatory Policy Update**
Panelists:

- Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA
- Sara Rothman, Special Assistant, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA

Panel Topics:

- Where are we now? Overview of regulatory policy documents released since the Fall 2015 Inter-governmental meeting
- Upcoming high priority policy issues

10:30 AM – 10:45 AM **Break**

10:45 AM – 11:00 AM **Remarks**
Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, FDA

11:00 AM – 12:15 PM **FDA Inspections and Enforcement Update**
Panelists:

- Ellen Morrison, Assistant Commissioner for Operations, Office of Regulatory Affairs (ORA), FDA
- Michael Levy, Deputy Director for Policy and Analysis, Office of Compliance, CDER/ FDA
- Kathleen Anderson, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA

Panel Topics:

- FDA inspections and enforcement update
- Changes in FDA inspectional procedures

12:15 PM – 1:30 PM **Lunch**

1:30 PM – 3:00 PM **Oversight of Pharmacies: Prescription Requirements**

Panelists:

- Sara Rothman, Special Assistant, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Daniel Kelber, Associate General Counsel, Division of Professional Regulation, Illinois Department of Financial and Professional Regulation
- Linda Bethman, Assistant Attorney General, Senior Counsel, Maryland Office of the Attorney General
- Sue Mears, Compliance Officer, Iowa Board of Pharmacy

Panel Topics:

- FDA Draft Guidance: Prescription Requirement under Section 503A of the Federal Food, Drug and Cosmetic Act
- State approaches to prescription requirements

Breakout Sessions:

- State laws and policies
- FDA and State enforcement

3:00 PM – 3:15 PM **Break**

3:15 PM – 4:30 PM **FDA/State Collaboration and Communication**

Panelists:

- Lauren DiPaola, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA
- Sara Ashton, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA
- Kathleen Anderson, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA
- Gail Bormel, Supervisory Consumer Safety Officer, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy
- Steven Saxe, Executive Director, Washington State Pharmacy Quality Assurance Commission

Panel Topics:

- State and FDA information needs
- Information sharing agreements

Facilitated open mic discussion

Wednesday, September 21, 2016 **8:20 AM – 4:45 PM**

8:20 AM – 8:30 AM **Welcome and Opening Remarks**
Brian Kehoe, Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation and Analysis, FDA

Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA

8:30 AM – 9:45 AM **Oversight of Pharmacies: Quality Standards & Insanitary Conditions**
Panelists:

- Ian Deveau, Branch Chief, Office of Compliance, CDER/FDA
- Emily Gebbia, Senior Advisor, Office of Compliance, CDER/FDA
- Gay Dodson, Executive Director/Secretary, Texas Board of Pharmacy
- Kimberly Leonard, Acting Executive Secretary; Pharmacy Supervisor, Practice and Registration, New York State Board of Pharmacy
- Kimberly Gaedeke, Director, Michigan Bureau of Professional Licensing

Panel Topics:

- Insanitary conditions at compounding facilities
- State-required compounding quality standards and State inspectional approaches

Facilitated open mic discussion

9:45 AM – 10:00 AM **Break**

10:00 AM – 11:30 AM **Oversight of Outsourcing Facilities: Panel Discussion**
Panelists:

- Gail Bormel, Supervisory Consumer Safety Officer, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Gabrielle Cosel, Policy Analyst, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
- Virginia Herold, Executive Officer, California State Board of Pharmacy
- Caroline Juran, Executive Director, Virginia Board of Pharmacy

Panel Topics:

- Issues related to FDA and State oversight of outsourcing facilities
- FDA recommendations on State oversight
- Related updates to NABP Model Act

11:30 AM – 11:45 AM **Remarks**
Robert M. Califf, Commissioner of Food and Drugs

11:45 AM – 1:00 PM **Lunch**

1:00 PM – 3:15 PM **Oversight of Outsourcing Facilities: Breakout Sessions**

- Licensure – State laws and policies for licensure and outsourcing facility dispensing
- Regulation – distribution and wholesaling, pharmacist supervision of compounding at outsourcing facilities
- Inspections – frequency of FDA inspections, State desire to conduct inspections and for related training
- Open discussion – achieving a functional outsourcing facility sector, issues not yet raised

3:15 PM – 3:30 PM **Break**

3:30 PM – 4:30 PM **Physician Compounding**

Panelists:

- Emily Gebbia, Senior Advisor, Office of Compliance, CDER/FDA
- Nadine Shehab, Senior Scientist, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
- Lisa Robin, Chief Advocacy Officer, Federation of State Medical Boards
- Cameron McNamee, Director of Policy and Communications, Ohio Board of Pharmacy
- Cheri Atwood, Director of Compliance, Mississippi Board of Pharmacy

Panel Topics:

- Oversight mechanisms
- Quality and safety

4:30 PM – 4:45 PM **Closing Remarks**

Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA