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- FDA Draft Guidance: Prescription Requirement under Section 503A of the Federal Food, Drug and Cosmetic Act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

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

Break

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

Remarks
Robert M. Califf, Commissioner of Food and Drugs

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