Federal-State Meeting to Discuss Pharmacy Compounding

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

AGENDA

Thursday, March 20, 2014 **8:00 AM – 4:30 PM**

8:00 AM – 9:00 AM **Registration**

9:00 AM – 10:15 AM **Welcome and Introduction**
Sally Howard, Deputy Commissioner for Policy, Planning, and Legislation, FDA

Overview of Compounding Quality Act and FDA's Plans for Implementation
Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA

10:15 AM – 12:15 PM **Federal/State Communications – Panel Discussion**

- Sarah Kotler, Deputy Director, Division of Freedom of Information, Office of the Commissioner, FDA
- Lauren DiPaola, Testimony Specialist, Office of Policy and Risk Management, Office of Regulatory Affairs, FDA

10:45 AM – 11:00 AM **Break**

Federal/State Communications – Panel Discussion (con't)

- Tista Ghosh, Deputy Chief Medical Officer, Colorado Department of Public Health and Environment
- Michele Weizer, Vice Chair, Florida Board of Pharmacy
- Jay Campbell, Executive Director, North Carolina Board of Pharmacy
- Q&A/Comments

12:15 PM – 1:30 PM **Lunch**

1:30 PM – 2:45 PM **Inspections of Sterile Compounding Facilities and Enforcement**

- Ellen Morrison, Assistant Commissioner for Operations, Office of Regulatory Affairs, FDA
- Mike Levy, Deputy Director for Policy and Analysis, Office of Compliance, Center for Drug Evaluation and Research, FDA
- John Clay Kirtley, Executive Director, Arkansas Board of Pharmacy
- Q&A/Comments

2:45 PM – 3:00 PM **Break**

3:00 PM – 4:15 PM **Regulating interstate distribution of compounded drugs pursuant to section 503A under a Memorandum of Understanding (MOU) with FDA**

- Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA
- Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
- Mark Johnston, Executive Director, Idaho Board of Pharmacy
- Q&A/Comments

4:15 PM – 4:30 PM **Closing Remarks**
Danielle Grote, Acting Director of Intergovernmental Affairs, FDA

Friday, March 21, 2014 **9:00 AM – 4:00 PM**

9:00 AM – 9:15 AM **Brief Welcome**
Danielle Grote, Acting Director of Intergovernmental Affairs, FDA

9:15 AM – 10:45 PM **State Adverse Event Reporting**

- Gerald Dal Pan, Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA
- Joseph Perz, Team Leader, Prevention and Response Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
- Marion Kainer, Director, Healthcare Associated Infections and Antimicrobial Resistance Program, Tennessee Department of Health
- Q&A/Comments

10:45 AM – 11:00 AM **Break**

11:00 AM – 12:15 PM **State Enforcement Priorities**

- Gay Dodson, Executive Director, Texas State Board of Pharmacy
- Virginia Herold, Executive Officer, California State Board of Pharmacy
- Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy
- Q&A/Comments

12:15 PM – 1:30 PM **Lunch**

1:30 PM – 2:45 PM **State Legislation/Regulation**

- Joy Johnson Wilson, Director, Health and Human Services Policy, National Conference of State Legislatures
- Cody Wiberg, Executive Director, Minnesota Board of Pharmacy
- Margaret Clifford, Chief Compliance Officer, New Hampshire Board of Pharmacy
- Mitra Gavgani, Chair, Sterile Compounding Sub-Committee, Maryland Board of Pharmacy
- Q&A/Comments

2:45 PM – 3:00 PM **Break**

3:00 PM – 3:45 PM	**Listening Session** Opportunity for States to share their views on other issues with FDA
3:45 PM – 4:00 PM	**Meeting Wrap Up** Margaret Hamburg, Commissioner of Food and Drugs, FDA