2015 Inter-governmental Working Meeting on Drug Compounding and Drug Supply Chain Security

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

AGENDA

Monday, November 16, 2015 **8:00 AM – 5:00 PM**

Drug Compounding

8:00 AM – 9:00 AM **Registration**

9:00 AM – 9:15 AM **Welcome and Introduction**
Stephen Ostroff, Acting Commissioner of Food and Drugs

9:15 AM – 10:30 AM **Compounding Regulatory Policy Update**
- Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA and Agency Lead on Compounding
- Q&A/Comments

10:30 AM – 10:45 AM **Break**

10:45 AM – 12:15 PM **Draft Standard Memorandum of Understanding between FDA and the States**
- Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA and Agency Lead on Compounding
- Beth Ferguson, Deputy Director, Minnesota Board of Pharmacy
- Kimberly Grinston, Executive Director, Missouri Board of Pharmacy
- Q&A/Comments

12:15 PM – 1:30 PM **Lunch**

1:30 PM – 2:30 PM **Information Sharing and Disclosure**
- Sarah Kotler, 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
- Daniel Kelber, Associate General Counsel, Illinois Department of Financial and Professional Regulation
- Caroline Juran, Executive Director, Virginia Board of Pharmacy
- Q&A/Comments

2:30 PM – 2:45 PM **Break**

2:45 PM – 4:15 PM **A Comparison of U.S. Pharmacopeial Convention General Chapter 797 to the Current Good Manufacturing Practice Regulations Enforced by FDA**

- Ian Deveau, Branch Chief, Office of Compliance, Office of Manufacturing Quality, Division of Drug Quality I, Global Compliance Branch 1, FDA
- Q&A/Comments

4:15 PM – 4:45 PM **Listening Session**

- Opportunity for states to share their views with FDA

4:45 PM – 5:00 PM **Closing Remarks**
Brian Kehoe, Acting Director of Intergovernmental Affairs, FDA

Tuesday, November 17, 2015 **9:00 AM – 4:45 PM**

9:00 AM – 9:15 AM **Welcome and Opening Remarks**
Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA and Agency Lead on Compounding

9:15 AM – 10:45 AM **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
- Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy
- Tera McConnell, Compliance Program Officer, Texas State Board of Pharmacy
- Q&A/Comments

10:45 AM – 11:00 AM **Break**

11:00 AM – 12:00 PM **State Handling of Outsourcing Facilities**

- Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
- Virginia Herold, Executive Officer, California State Board of Pharmacy
- Allison Dudley, Executive Director, Florida Board of Pharmacy
- Michael Dupuis, Executive Director, New Hampshire Board of Pharmacy
- Q&A/Comments

12:00 PM – 1:00 PM **Lunch**

Drug Supply Chain Security

1:00 PM – 1:15 PM **Welcome and Introduction**

- Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, FDA

1:15 PM – 1:30 PM **Overview of DSCSA Implementation**

- Ilisa Bernstein, Deputy Director, Office of Compliance, Center for Drug Evaluation and Research, FDA
- Q&A/Comments

1:30 PM – 3:15 PM **Wholesale Distributor and Third-Party Logistics (3PL) Provider Licensing**

- Melissa Kim, Regulatory Counsel, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, FDA
- Diane Goyette, Regulatory Counsel, Medical Products and Tobacco Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, FDA
- Virginia Herold, Executive Officer, California Board of Pharmacy
- Renee Alsobrook, Compliance & Enforcement Manager, Florida Department of Business and Professional Regulation
- Cindy Hamilton, Chief Compliance Officer, Oklahoma Board of Pharmacy
- Q&A/Comments

3:15 PM – 3:30 PM **Break**

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

- Eleni Anagnostiadis, Division Director, Division of Drug Supply Chain Integrity, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, FDA
- Lauren DiPaola, Testimony Specialist, Office of Regulatory Affairs, FDA
- Caroline Juran, Executive Director, Virginia Board of Pharmacy
- Fiona Karbowicz, Pharmacist Consultant, Oregon Board of Pharmacy
- Q&A/Comments

4:15 PM – 4:30 PM **Open Microphone**

4:30 PM – 4:45 PM **Closing Remarks**

Ilisa Bernstein, Deputy Director, Office of Compliance, Center for Drug Evaluation and Research, FDA