2015 Inter-governmental Working Meeting on Drug Compounding

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

AGENDA

Wednesday, March 18, 2015 **8:00 AM – 4:15 PM**

8:00 AM – 9:00 AM **Registration**

9:00 AM – 9:15 AM **Welcome and Introduction**
Stephen Ostroff, Chief Scientist, FDA

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

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
- Gail Bormel, Acting Associate Director, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research, FDA
- Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
- John Kirtley, Executive Director, Arkansas State Board of Pharmacy
- Mark Johnston, Executive Director, Idaho State Board of Pharmacy
- Q&A/Comments

12:15 PM – 1:30 PM **Lunch**

1:30 PM – 3:00 PM **Registration of Outsourcing Facilities**

- Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, FDA
- Virginia Herold, Executive Officer, California State Board of Pharmacy
- Linda Bethman, Board Counsel, Maryland Board of Pharmacy
- Cheri Atwood, Director of Compliance, Mississippi Board of Pharmacy
- Q&A/Comments

3:00 PM – 4:00 PM **Listening Session on Compounding Regulatory Policy**[1]
Opportunity for states to share their views with FDA on issues related to regulatory policy discussed in the sessions on the first day, and not scheduled for discussion on March 19

4:00 PM – 4:15 PM **Closing Remarks**
Danielle Grote, Director of Intergovernmental Affairs, FDA

Thursday, March 19, 2015 **9:00 AM – 4:15 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 **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
- Caroline Juran, Executive Director, Virginia Board of Pharmacy
- Jay Campbell, Executive Director, North Carolina Board of Pharmacy
- Q&A/Comments

10:45 AM – 11:00 AM **Break**

11:00 AM – 12:30 PM **Inspections of Sterile Compounding Facilities and Enforcement**
- Alonza Cruse, Acting Director, Office of Medical Products and Tobacco Operations, Office of Regulatory Affairs, FDA
- Mike Levy, Deputy Director for Policy and Analysis, Office of Compliance, Center for Drug Evaluation and Research, FDA
- Gay Dodson, Executive Director, Texas State Board of Pharmacy
- Q&A/Comments

12:30 PM – 1:30 PM **Lunch**

1:30 PM – 3:00 PM **Animal Drug Compounding**
- Eric Nelson, Director, Center for Veterinary Medicine, Division of Compliance, FDA
- Hal Wand, Executive Director, Arizona Board of Pharmacy
- Steve Hart, Pharmacy Inspections and Investigations Coordinator, Kentucky Board of Pharmacy
- Q&A/Comments

[1] *Note: A separate listening session has been scheduled for the second day to include issues related to inspections and enforcement, information sharing and disclosure, animal drug compounding, and any remaining issues.*

3:00 PM – 3:15 PM	**Break**
3:15 PM – 4:00 PM	**Listening Session** Opportunity for states to share their views with FDA on any remaining topics
4:00 PM – 4:15 PM	**Closing Remarks** Danielle Grote, Director of Intergovernmental Affairs, FDA