INTERGOVERNMENTAL WORKING MEETING ON DRUG COMPOUNDING - 2018

AGENDA

White Oak Campus, Great Room
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

U.S. FOOD & DRUG ADMINISTRATION

Tuesday, September 25, 2018 **8:00 AM – 5:15 PM**

8:00 AM – 8:30 AM **Registration**

8:30 AM – 9:15 AM **Welcome and Introduction**

- Nick Alexander, JD, Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation, and Analysis (OPPLA), FDA
- Anna Abram, Deputy Commissioner for Policy, Planning, Legislation, and Analysis, OPPLA, FDA
- Julie Dohm, JD, PhD, Senior Science Advisor for Compounding, Center for Drug Evaluation and Research (CDER); Agency Lead for Compounding, FDA

9:15 AM – 10:15 AM **State Legislative and Regulatory Updates**

- Shelley Rosebrook, RPh, Licensed Pharmacy Inspector/Investigator, Kansas State Board of Pharmacy
- William Frisch, Jr., RPh, Director of Pharmacy Compliance, Massachusetts Board of Registration in Pharmacy
- Michelle Chan, RPh, Quality Assurance Pharmacist, Massachusetts Board of Registration in Pharmacy
- Carrie C. Phillips, MS, PharmD, Executive Officer, Pharmacy Board, Office of Professional Regulation, State of Vermont
- Eileen Lewalski, PharmD, JD, Professional Affairs Senior Manager, National Association of Boards of Pharmacy (NABP)
- Elizabeth Scott “Scotti” Russell, Government Affairs Manager, NABP

10:15 AM – 10:30 AM **Break**

10:30 AM – 11:30 AM **FDA-State Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products**

- Sara Rothman, MPH, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA
- Reginald Dilliard, DPh, Executive Director, Tennessee Board of Pharmacy
- Anthony Rubinaccio, RPh, Executive Director, New Jersey Board of Pharmacy
- Melissa Madigan, PharmD, JD, Policy and Communications Director, NABP
- Eileen Lewalski, PharmD, JD, Professional Affairs Senior Manager, NABP

11:30 AM – 12:30 PM **Memorandum of Understanding – Breakout Sessions**

12:30 PM – 1:45 PM **Lunch**

1:45 PM – 2:45 PM **Use of Compounded Drugs when an Approved Drug Is Available**

- Gabrielle Cosel, MSc, Policy Analyst, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA
- Beth O'Halloran, RPh, Deputy Executive Director, Virginia Board of Pharmacy
- Jenni Wai, RPh, Chief Pharmacist, State of Ohio Board of Pharmacy

2:45 PM – 3:15 PM **Compounding and Repackaging of Radiopharmaceuticals**

- Sara Rothman, CDER, FDA

3:15 PM – 3:30 PM **Break**

3:30 PM – 5:00 PM **Drug Supply Chain Security Act Implementation**

- Connie Jung, RPh, PhD, Senior Advisor for Policy, Office of Drug Security, Integrity, and Recalls (ODSIR), Office of Compliance, CDER, FDA
- Tia Harper-Velasquez, PharmD, JD, Branch Chief, Supply Chain Strategy and Policy Branch, ODSIR, Office of Compliance, CDER, FDA

5:00 PM – 5:15 PM **Closing Remarks**

Wednesday, September 26, 2018 **8:00 AM – 4:45 PM**

8:00 AM – 8:30 AM **Registration**

8:30 AM – 8:40 AM **Opening Remarks**

- Nick Alexander, OPPLA, FDA
- Julie Dohm, CDER, FDA

8:40 AM – 10:00 AM **Insanitary Conditions in Compounding Facilities and CGMP Requirements for Outsourcing Facilities**

- Ian Deveau, PhD, Branch Chief, Office of Manufacturing Quality, Office of Compliance, CDER, FDA

10:00 AM – 10:15 AM **Insanitary Conditions – Policy Update**

- Sara Rothman, CDER, FDA

10:15 AM – 10:30 AM **Break**

10:30 AM – 11:00 AM **Notes from the Field: FDA Investigator Perspectives**

- Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, Office of Regulatory Affairs (ORA), FDA

- June Page, PharmD, LCDR, U.S. Public Health Service, Investigator, ORA, FDA

11:00 AM – 12:00 PM **Oversight of Drug Compounding**

- Kathleen Anderson, PharmD, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA
- C. Erica White, MBA, JD, Executive Director, Florida Board of Pharmacy
- Eric Griffin, Director of Compliance and Enforcement, State of Ohio Board of Pharmacy
- Krystal Brashears Stefanyk, Director of Inspections, North Carolina Board of Pharmacy

12:00 PM – 1:15 PM **Lunch**

1:15 PM – 1:45 PM **Use of Bulk Drug Substances in Compounding**

- Rosilend A. Lawson, VMD, JD, Lead Regulatory Counsel, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA
- Ruey Ju, PharmD, JD, Senior Advisor for Compounding and Compliance and Enforcement, Office of Compliance, CDER, FDA

1:45 PM – 2:00 PM **Outsourcing Facility Oversight**

- Edisa Gozun, Branch Chief, Compounding and Pharmacy Practices Branch, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA

2:00 PM – 2:45 PM **Outsourcing Facility Oversight – Breakout Sessions**

2:45 PM – 3:00 PM **Break**

3:00 PM – 3:45 PM **Open Forum – Tabletop Discussions**

3:45 PM – 4:30 PM **Outsourcing Facility Oversight – Readout and Panel**

- Edisa Gozun, CDER, FDA
- Gail Bormel, JD, RPh, Director, Division of Prescription Drugs, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA
- C. Erica White, MBA, JD, Executive Director, Florida Board of Pharmacy
- Reginald Dilliard, Tennessee Board of Pharmacy
- Susan Alverson, Director of Regulatory Affairs, Alabama Board of Pharmacy
- Elizabeth Scott “Scotti” Russell, NABP

4:30 PM – 4:45 PM **Closing Remarks**