Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock

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

AGENDA

Tuesday, May 21, 2018 **8:30 AM – 2:00 PM**

8:30 AM – 9:00 AM **Registration**

9:00 AM – 9:05 AM **Welcome remarks**
Donald D. Ashley, JD, Director, Office of Compliance, CDER, FDA

9:05 AM – 9:15 AM **Overview of meeting purpose and discussion topics**
Gail Bormel, JD, RPh, Director, Division of Compounded Drugs, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA

9:15 AM – 9:45 AM **Overview of Revised Draft Guidance: Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities**
Marci Kiester, PharmD, MS, RAC, CAPT, USPHS, Senior Policy Analyst, Office of Pharmaceutical Quality, CDER, FDA

9:45 AM – 10:00 AM **Break**

10:00 AM – 11:30 AM **Provider perspectives and discussion**

10:00 AM – 10:20 AM David Glasser, MD, American Academy of Ophthalmology
10:20 AM – 10:40 AM Damien F. Goldberg, MD, American Society of Cataract and Refractive Surgery
10:40 AM – 11:00 AM John T. Thompson, MD, American Society of Retina Specialists

11:00 AM – 11:30 AM **Moderated Discussion**

11:30 AM – 12:30 PM **Lunch**

12:30 PM – 2:00 PM **Outsourcing facility and supplier perspectives and discussion**

12:30 PM – 12:50 PM Lee Rosebush, PharmD, JD, Outsourcing Facility Association
12:50 PM – 1:10 PM A.J. Day, PharmD, RPh, Professional Compounding Centers of America

1:10 PM – 2:00 PM **Moderated Discussion**

2:00 PM **Adjourn**