

**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

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|---------------------|--|
| 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| 9:15 AM – 9:45 AM | Overview of Revised Draft Guidance: Current Good Manufacturing Practice—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 |