AGENDA

GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Food and Drug Administration – White Oak Campus
Building 31 – The Great Room, B & C
Silver Spring, MD

May 14, 2015

Panel Chairperson
Mark A. Talamini, M.D.

Designated Federal Officer
Natasha G. Facey

8:00 a.m.
Call to Order
Panel Introduction
Conflict of Interest Statement

8:15 a.m.
Center for Devices and Radiological Health
Part I: FDA Opening Remarks
Stephen Ostroff, M.D., FDA Commissioner (Acting)

Part II: Timeline of Events
Suzanne Schwartz, M.D., M.B.A

Part III: Introduction to Endoscopic Retrograde Cholangiopancreatography (ERCP)
Herb Lerner, M.D.

Part IV: Overview of Duodenoscopes and Reprocessing Procedures
Shani Haugen, Ph.D.

Part V: Automated Endoscope Reprocessors (AERs) and Sterilization
Elaine Mayhall, Ph.D.

Part V: Medical Device Adverse Event Reports
Jose Delgado Donayre, M.D.

9:30 a.m.
Clarifying Questions from the Panel

9:45 a.m.
Break

10:00 a.m.
Manufacturer Presentations
May 14, 2015

11:00 a.m. Clarifying Questions from the Panel
11:15 a.m. **Infections: Hospitals’ Perspective**
11:45 a.m. Clarifying Questions from the Panel
12:00 p.m. **Lunch**
1:00 p.m. Open Public Hearing*
2:00 p.m. Clarifying Questions from the Panel
2:15 p.m. **Infections: Hospitals’ Perspective (continued)**
3:15 p.m. Clarifying Questions from the Panel
3:30 p.m. **Break**
3:45 p.m. **CDC Outbreak Investigation**
            Alexander J. Kallen, M.D., M.P.H.
4:15 p.m. Clarifying Questions from the Panel
4:30 p.m. **FDA Outbreak Investigation**
            Suzanne Schwartz, M.D., M.B.A.
4:45 p.m. Clarifying Questions from the Panel
5:00 p.m. **Reprocessing Verification Testing**
            Michelle Alfa, Ph.D.
5:30 p.m. Clarifying Questions from the Panel
5:45 p.m. Session Adjournment

*Open Public Hearing:* Interested persons may present data, information or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the Panel will speak at this time. After they have spoken, the Chair may ask them to remain if the Panel wishes to question them. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair.
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GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
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MEDICAL DEVICES ADVISORY COMMITTEE

Food and Drug Administration – White Oak Campus
Building 31 – The Great Room, Room B & C
Silver Spring, MD

May 15, 2015

Panel Chairperson
Mark A. Talamini, M.D.

Designated Federal Officer
Natasha G. Facey

8:00 a.m. Call to Order
Panel Introduction
Conflict of Interest Statement

8:15 a.m. FDA: Recap of Day 1

8:30 a.m. CDC Surveillance Protocols
Matthew Arduino, M.S., Dr.PH.

9:00 a.m. Clarifying Questions from the Panel

9:15 a.m. Open Public Hearing*

10:15 a.m. Clarifying Questions from the Panel

10:30 a.m. Break

10:45 a.m. ERCP Scopes: A Need to Shift from Disinfection to Sterilization?
William Rutala, Ph.D., M.P.H.

11:15 a.m. Clarifying Questions from the Panel

11:30 a.m. Ethylene oxide sterilization – EPA perspective
Timothy Leighton

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12:00 p.m. Clarifying Questions from the Panel
12:15 p.m. **Lunch**
1:15 p.m. Panel Deliberations
2:00 p.m. FDA Questions to the Panel
3:00 p.m. **Break**
3:15 p.m. FDA Questions to the Panel (continued)
4:30 p.m. FDA Summations
5:00 p.m. Meeting Adjournment