



AGENDA

**GENERAL AND PLASTIC SURGERY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE**

Hilton Washington DC North/Gaithersburg

September 20, 2016

- 8:00 a.m. Call to Order **Hobart W. Harris, M.D.**
Introduction of Committee **Chairperson**
- Conflict of Interest Statement **Evella F. Washington**
Designated Federal Officer
- 8:15 a.m. Opening Remarks
Robert Califf, M.D., FDA Commissioner
- 8:30 a.m. OMPT/Office of Combination Products
Part 1: Overview of Combination Products
Melissa Burns, Office of Combination Products
- 8:45 a.m. Part 2: Regulatory History and Current Regulatory Pathways for Wound Dressings
History
Charles Durfor, Ph.D., Division of Surgical Devices
- Current Regulatory pathways*
Cynthia Chang, Ph.D., Division of Surgical Devices
- Types of testing/evaluation methods*
Brandon Kitchel, Division of Surgical Devices
- Part 3: Clinical Perspectives on Unclassified Wound Dressings
Premarket
Laura Marquart, M.D., Division of Surgical Devices
- Postmarket-Office of Surveillance and Biometrics*
Karen Nast, M.S., R.N., Division of Post-Market Surveillance

AGENDA, continued

September 20, 2016

- 10:00 a.m. Clarifying Questions from the Panel
- 10:20 a.m. **Break**
- 10:40 a.m. Part 4: Benefit/Risk (individual and societal) considerations for Antimicrobial Agents in Wound Dressings
Brandon Kitchel, Division of Surgical Devices
- 11:00 a.m. Guest Speaker
Finn Gottrup, M.D., DMSci.
- 11:45 a.m. Clarifying Questions from Panel
- 12:00 p.m. **Lunch**
- 1:00 p.m. *Open Public Hearing**
- 2:00 p.m. Overview: Charge to the Committee
Robert Califf, M.D., FDA Commissioner
- 2:15 p.m. Panel Discussion Questions Part 1
- 3:00 p.m. **Break**
- 3:10 p.m. Panel Discussion Questions Part 2
- 3:20 p.m. Panel Discussion
- 4:45 p.m. FDA Summations
- 5:00 p.m. Meeting 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.