

## AGENDA – Day 1

### Obstetrics & Gynecology Medical Devices Panel

Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD

September 8<sup>th</sup> and 9<sup>th</sup>, 2011

#### Panel Chairman

Tommaso Falcone, M.D.

#### Designated Federal Officer

Shanika Craig, MBA

### Discussion and Recommendations Regarding the Safety and Effectiveness of Surgical Mesh Used for Repair of Pelvic Organ Prolapse (POP)

#### September 8, 2011 – POP

- 8:00 - 8:15     **Call to Order**  
Conflict of Interest Statement  
Panel Introductions
- 8:15 - 8:30     **Introductory Remarks**  
Herbert P. Lerner, MD  
Director (Acting), Division of Reproductive, Gastro-Renal, and Urological Devices  
Office of Device Evaluation, Center for Devices and Radiological Health (CDRH)
- 8:30 - 8:50     **FDA Reclassification Process**  
Marjorie Shulman  
Director (Acting), Premarket Notification Staff  
Office of Device Evaluation, CDRH
- 8:50 - 9:10     **522 Postmarket Studies**  
Mary Beth Ritchey, PhD  
Associate Director, Division of Epidemiology  
Office of Surveillance and Biometrics, CDRH
- 9:10 - 11:00    **Open Public Hearing\***
- 11:00 - 11:15   **Break**
- 11:15 - 11:45   **Industry Presentations**
- 11:45 - 12:45   **Lunch**

**\*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.

**AGENDA – Day 1 (cont'd)**

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**Discussion and Recommendations Regarding the Safety and Effectiveness  
of Surgical Mesh Used for Repair of Pelvic Organ Prolapse (POP)**

**September 8, 2011 – POP**

12:45 - 1:45     **FDA Presentation**

***MDR Overview of Reported Adverse Events***

Nancy Pressly

Associate Division Director

Division of Postmarket Surveillance, Office of Surveillance & Biometrics, CDRH

***Epidemiological Overview & Need for Postmarket Studies***

Colin Anderson-Smits, MPH

Epidemiologist, Epidemiology Evaluation & Research I

Division of Epidemiology, Office of Surveillance & Biometrics, CDRH

***Clinical Perspective***

Jill Brown, MD/MPH, FACOG

Clinical Reviewer, Ob/Gyn Devices Branch

DRGUD, Office of Device Evaluation, CDRH

***FDA Conclusion***

Julia Carey-Corrado, MD, MS

Clinical Reviewer, Ob/Gyn Devices Branch

DRGUD, Office of Device Evaluation, CDRH

1:45 - 3:15     **FDA Questions to the Panel and Panel Deliberations**

3:15 - 3:30     **Break**

3:30 - 5:45     **FDA Questions to the Panel and Panel Deliberations (cont'd)**

5:45 - 6:00     **Summary and Next Steps**

6:00 PM         **Adjournment**

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