AGENDA – Day 1
Obstetrics & Gynecology Medical Devices Panel
Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD
September 8 and 9, 2011

Panel Chairman       Designated Federal Officer
Tommaso Falcone, M.D.                   Shanika Craig, MBA

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

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, M.D.
Director (Acting), Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)
Office of Device Evaluation, Center for Devices and Radiological Health (CDRH)

8:30- 8:45   FDA Reclassification Process
Marjorie Shulman
Acting Director, Premarket Notification Staff
Office of Device Evaluation, CDRH

8:45-9:00   522 Premarket Studies
Mary Beth Ritchey, Ph.D.
Associate Director, Division of Epidemiology
Division of Epidemiology Office of Surveillance and Biometrics, CDRH

9:00- 9:10   Questions from the Panel

9:10- 11:20  Open Public Hearing*

11:20- 11:30 Questions to Open Public Hearing Speakers

11:30- 11:40 Break

11:40- 12:35 Industry Presentations

12: 35- 12:45 Questions to Industry

*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)
September 8, 2011 – POP

12:45- 1:45    Lunch

1:45- 2:55    FDA Presentation

**MDR Overview of Reported Adverse Events**
Nancy Pressly
Associate Division Director
Division of Postmarket Surveillance, Office of Surveillance & Biometrics

**Epidemiological Overview & Need for Postmarket Studies**
Colin Anderson-Smits, MPH
Epidemiologist, Epidemiology Evaluation & Research I
Division of Epidemiology, Office of Surveillance & Biometrics

**Clinical Perspective**
Jill Brown, M.D.
Clinical Reviewer, Ob/Gyn Devices Branch
DRGUD/Office of Device Evaluation

**FDA Conclusion**
Julia Corrado, M.D.
Clinical Reviewer, Ob/Gyn Devices Branch
DRGUD/Office of Device Evaluation

2:55-3:05    Questions from the Panel

3:05- 4:50    FDA Questions to the Panel and Panel Deliberations

4:50- 5:00    Break

5:00- 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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