AGENDA – Day 2
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 Female Stress Urinary Incontinence

September 9, 2011 – SUI

8:00- 8:15    Call to Order
              Conflict of Interest Statement
              Panel Introductions

8:15- 8:30   FDA Introductory Remarks (recap)
              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- 8:50   522 Premarket Studies
              Mary Beth Ritchey, Ph.D.
              Associate Director, Division of Epidemiology
              Division of Epidemiology Office of Surveillance and Biometrics, CDRH

8:50- 9:00   Questions from the Panel

9:00- 10:10  Open Public Hearing*

10:10- 10:20 Questions to Open Public Hearing Speakers

10:20- 10:30 Break

10:30- 11:20 Industry Presentations

11:20- 11:30 Questions to Industry

11:30- 12:30 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 2 (Cont’d)
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12:30- 1:30      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
  Cara Krulewitch, CNM, Ph.D.
  Chief, Epidemiology Evaluation & Research I
  Division of Epidemiology, Office of Surveillance & Biometrics

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

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

1:30- 1:40      Questions from the Panel

1:40- 2:30      FDA Questions to the Panel and Panel Deliberations

2:30- 2:40      Break

2:40- 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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