CIRCULATORY SYSTEM DEVICES PANEL

AGENDA

Amplatzer™ PFO Occluder

May 24, 2016

8:00 a.m. Call to Order
Richard Page, MD
Introduction of Committee
Chairperson
Conflict of Interest Statement
Evella Washington
Designated Federal Officer

8:15 a.m. Sponsor Presentation

9:45 a.m. Sponsor Q&A

10:00 a.m. Break

10:15 a.m. FDA Presentation

11:45 a.m. FDA Q&A

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Panel Deliberations

3:15 p.m. Break

3:30 p.m. FDA Questions to the Panel

5:00 p.m. FDA and Sponsor Summations

5:30 p.m. Panel Vote

6:00 p.m. 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. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.