

DEPARTMENT OF HEALTH & HUMAN SERVICES

CIRCULATORY SYSTEM DEVICES PANEL **AGENDA**

March 15, 2016

Circulatory System Devices Panel Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System

Holiday Inn Gaithersburg MD

8:00 a.m. Call to Order

Introduction of Committee

Conflict of Interest Statement

Richard Page, MD Chairperson

CDR Dimitrus Culbreath

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.