

*AGENDA*

**CIRCULATORY SYSTEM DEVICES PANEL  
of the  
MEDICAL DEVICES ADVISORY COMMITTEE**

Hilton Washington DC North/Gaithersburg  
Grand Ballroom  
620 Perry Pkwy., Gaithersburg, MD 20877

*June 3, 2016*

- |            |                                                                                                                                          |                                                           |
|------------|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| 8:00 a.m.  | Call to Order<br>Introduction of Committee<br>Statement of purpose                                                                       | <b>Richard A. Lange, MD</b><br>Chairperson                |
|            | Conflict of Interest Statement                                                                                                           | Evella F. Washington<br><b>Designated Federal Officer</b> |
| 8:15 a.m.  | FDA: Recap of Day 1<br><b>Suzanne Schwartz, MD, MBA</b>                                                                                  |                                                           |
| 8:30 a.m.  | <i>M. chimaera</i> and heater-cooler units: “Lessons learned from the University of Iowa outbreak response”<br><b>Daniel Diekema, MD</b> |                                                           |
| 9:00 a.m.  | NTM Infections-Clinical Presentation<br><b>Charles Daley, MD</b>                                                                         |                                                           |
| 9:15 a.m.  | Whole Genome Analysis of Nontuberculous Mycobacteria, including <i>Mycobacterium chimaera</i><br><b>Michael Strong, Ph.D.</b>            |                                                           |
| 9:30 a.m.  | Clarifying Questions from the Panel                                                                                                      |                                                           |
| 9:45 a.m.  | FDA Questions to the Panel                                                                                                               |                                                           |
| 10:15 a.m. | <b>Break</b>                                                                                                                             |                                                           |
| 10:30 a.m. | FDA Questions to the Panel (continued)                                                                                                   |                                                           |

*AGENDA, continued*

*June 3, 2016*

12:00 p.m.    **Lunch**

1:00 p.m.    FDA Questions to the Panel (continued)

3:00 p.m.    **Break**

3:15 p.m.    FDA Questions to the Panel (continued)

4:30 p.m.    FDA Summations

5:00 p.m.    Meeting 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. 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.