

AGENDA

Microbiology Medical Devices Panel OF MEDICAL DEVICES ADVISORY COMMITTEE

Food and Drug Administration - White Oak Campus
Building 31 – The Great Room, Room 1503
Silver Spring, MD

August 16, 2016

Acting Panel Chairperson
Angela Caliendo, M.D.

Designated Federal Officer
Shanika Craig, MHA, MBA

Over the Counter Diagnostic Assays for Infectious Disease

- 8:00 a.m. Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
FDA Update**
- 8:30 a.m. FDA Presentation**
- 9:00 a.m. Q & A**
- 9:15 a.m. Break**
- 9:30 a.m. Outside Speaker Presentations**
- 10:30 a.m. Q & A**
- 10:45 p.m. Panel Deliberations**
- 12:00 p.m. Lunch**
- 1:00 p.m. Open Public Hearing***
- 2:30 p.m. Panel Deliberations**
- 3:45 p.m. Break**
- 3:55 p.m. FDA Questions**
- 5:20 p.m. FDA 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.