

# AGENDA

## Microbiology Devices Panel of the MEDICAL DEVICES ADVISORY COMMITTEE

Hilton Gaithersburg  
620 Perry Parkway  
Gaithersburg, MD

June 13, 2013

8:00 a.m.	Call to Order Introduction of Committee	<b>Angela M. Caliendo, M.D.</b> Chairperson
	Conflict of Interest Statement	<b>Shanika Craig, M.H.A., M.B.A.</b> Designated Federal Officer
8:20 a.m.	Reclassification Presentation	<b>Jean Cooper, D.V.M.</b> Senior Policy Analyst Office of In Vitro Diagnostics and Radiological Health (OIR)
8:35 a.m.	Clarifying Questions from Committee	
8:45 a.m.	FDA Presentation	
9:30 a.m.	Clarifying Questions from Committee	
9:45 a.m.	Guest Speaker	
10:15 a.m.	Clarifying Questions from Committee	
10:30 a.m.	Break	
10:40 a.m.	Guest Speaker	
11:10 a.m.	Clarifying Questions from Committee	
11:25 a.m.	Panel Deliberations	
12:30 p.m.	<b>LUNCH</b>	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Committee Questions to Open Public Hearing Speakers	
2:40 p.m.	Panel Deliberations	
3:10 p.m.	Break	
3:20 p.m.	FDA Questions to the Panel	
5:20 p.m.	Summation	
5:30 p.m.	Adjournment	