

FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
117th Meeting of the Blood Products Advisory Committee
Joint Meeting with the Medical Devices Advisory Committee (Microbiology Devices Panel)
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 22, 2018

AGENDA

11:25-11:40 a.m.	Questions for the speakers	(15')
11:40-11:50 a.m.	Break	(10')
11:50-12:10 p.m.	FDA Perspective on Benefit/Risk of HCV Serology And Molecular Assay Reclassification	Ines Garcia, Ph.D. CDRH, FDA (20')
12:10- 12:55 p.m.	Lunch	(45')
12:55- 1:15 p.m.	Molecular Tests for the Detection, Quantitation and/or Genotyping of HCV RNA	Silke Schlottmann, Ph.D. CDRH, FDA (20')
1:15-1:45 p.m.	Questions to FDA	(30')
1:45- 2:45 p.m.	Open Public Hearing	(60')
2:45- 5:00 p.m.	Questions to the panel and deliberations	(135')
5:00 p.m.	Summary and Adjourn	Uwe Scherf, Ph.D. CDRH, FDA (5')

March 22, 2018