

**Microbiology Medical Devices Panel
of the
MEDICAL DEVICES ADVISORY COMMITTEE**

**Holiday Inn, Gaithersburg
November 9, 2016**

Panel Chairperson
Cathy Petti, M.D.

Designated Federal Officer
Aden Asefa, M.P.H.

Reclassification of quantitative CMV viral load devices from Class III to Class II

- 8:00 a.m.** **Call to Order**
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
- 8:15 a.m.** **Welcome & Introduction (U. Scherf, FDA)**
- 8:25 a.m.** **Background of CMV regulatory path and Intended Uses**
(S. Gitterman, FDA) [15']
- 8:35 a.m.** **Clinical aspects of viral load testing for CMV**
(A. Limaye, University of Washington) [20'/5' questions]
- 9:00 a.m.** **Technical issues with CMV viral load testing and standards**
(L. Cook, University of Washington) [20'/5' questions]
- 9:25 a.m.** **FDA perspective on benefit/risk of reclassification**
(K. Whitaker, FDA)
- 9:55 a.m.** **Break**
- 10:15 a.m.** **Open Public Hearing (CMV)***
- 11:00 a.m.** **Panel Deliberations**
- 12:00 p.m.** **Lunch**
- 1:00 pm** **Questions to the Panel (S. Gitterman, FDA)**
- 2:20 p.m.** **Break**

Benefit/Risk Discussion of EBV and BK Viruses in Transplant Patients

- 2:30 p.m.** **Introduction (S. Gitterman, FDA) [10']**
- 2:40 pm** **Clinical aspects of EBV quantitative viral load testing and BK testing in transplant patients**
 (A. Limaye, University of Washington) [20'/5' questions]
- 3:05 pm** **Measurement of EBV Viral load in the laboratory**
 (L. Cook, University of Washington) [20'/5' questions]
- 3:30 p.m.** **Open Public Hearing***
- 4:00 pm** **Panel Discussion**
- 6:00 p.m.** **Adjourn**

*** 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.