



Microbiology Devices Panel for the Medical Devices Advisory Committee

**Hilton Washington, DC/North. Salons A-D of Ballroom
March 8, 2019**

Discuss and make recommendations regarding new or alternative approaches to the development and evaluation of devices detecting Human Papillomavirus (HPV) nucleic acid. Topics to be addressed include study design, comparator methods, and device indications for use.

Panel Chairperson:

Barbara VanDerPol, Ph.D., M.P.H

Designated Federal Officer

Aden S. Asefa, M.P.H.

8:00	a.m.	Call to Order Conflict of Interest Panel Introductions
8:15	a.m.	Welcome & Introduction (FDA)
8:30	a.m.	Guest Speaker Presentation (45 min) <i>Speaker: Dr. Mark Schiffman</i>
9:15	a.m.	Questions to speaker (15 min)
9:30	a.m.	FDA Presentation (45 min) <i>Speaker: Dr. Luna Zaritsky</i>
10:15	a.m.	Questions to FDA (15 min)
10:30	a.m.	Break
10:45	a.m.	Open Public Hearing*
12:00	p.m.	Lunch
01:00	p.m.	Panel Deliberations
03:00	p.m.	Break
03:15	p.m.	FDA Questions/Panel Deliberations Cont.
04:15	p.m.	Panel Vote
05:00	p.m.	Summary of Panel Recommendations

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.