

DRAFT AGENDA  
Meeting of the  
MICROBIOLOGY DEVICES PANEL MEETING  
Friday, March 8, 2002

*Panel Chair: Michael L. Wilson, M.D.*  
*Executive Secretary/ Chief, Bacteriology Branch: Freddie M. Poole*  
*Division Director: Steven I. Gutman, M.D., M.B.A.*

**8:30 CALL TO ORDER**

Opening Remarks.....Executive Secretary  
Introduction of Panel.....Panel Chair

**NEW BUSINESS**

**PREMARKET APPROVAL SUPPLEMENT: Digene High Risk HPV DNA**

A nucleic acid hybridization in vitro diagnostic device for the detection of thirteen high-risk types of human papillomavirus (HPV) in cervical specimens. The test as modified is indicated for use as a general population screening test in conjunction with the Papanicolaou smear for women 30 years of age and older, as an aid to determine the absence of high-grade cervical disease or cancer.

**9:00 MANUFACTURER'S PRESENTATION:**

Mark A. Del Vecchio..... Tab #1  
Director, Regulatory and Clinical Affairs, Digene Corporation

Atilla Lorincz, Ph.D..... Tab #2  
Senior Vice President and Chief Scientific officer, Digene Corporation

Jonathan Kahn, Esq.....Summary Tab #3  
Regulatory Consultant for Digene  
Partner, Hogan and Hartson, LLP

**10:15 BREAK**

**10:25 PANEL DISCUSSANT:**

Elizabeth Unger, Ph.D., M.D.....  
Chief, Human Papillomavirus Section, DVRD/NCID, CDC

Herschel Lawson, M.D.....  
Medical Advisor, Program Services Branch, DCPC, NCCDPHP, CDC

**10:45 FDA PRESENTATION:**

Thomas E. Simms.....FDA Issues  
Sr. Review Scientist, Virology Branch, DCLD

Marina Kondratovich, Ph.D.....Statistical Study  
Mathematical Statistician, Division of Biostatistics, Office of Surveillance & Biometrics, CDRH

**11:30 OPEN PUBLIC HEARING**

*(Public Attendees who have contacted the Executive Secretary prior to the meeting, will address the panel and present information relevant to nucleic acid hybridization in vitro diagnostic devices for the detection of high-risk types of human papillomavirus (HPV) in cervical specimens. Speakers are to state whether or not they have any financial involvement with manufacturers of these devices.)*

**12:00 LUNCH BREAK**

**1:00 OPEN COMMITTEE DISCUSSION**

*(This portion of the meeting is open to public observers. However, public observers may not participate except at the specific request of the Chairperson.)*

**2:45 BREAK**

**3:00 OPEN PUBLIC HEARING**

*(This portion of the meeting is open for comments from the public to comment on related issues.)*

**3:30 INDUSTRY RESPONSE**

*(The Sponsor may provide comments to respond to any issue raised during the Committee Discussion.)*

**3:35 FDA RESPONSE**

*(The FDA may provide comments to respond to any issue raised during the Committee Discussion.)*

**3:40 FINAL RECOMMENDATIONS AND VOTE**

*(The Panel will provide final recommendations to the FDA and vote on the PMA Supplement.)*

**4:30 ADJOURN**