



AGENDA  
**HEMATOLOGY AND PATHOLOGY DEVICES PANEL MEETING**  
Hilton Washington DC North, Gaithersburg, MD  
October 23, 2009

**Panel Chairperson**  
Dorothy Adcock, M.D.

**Designated Federal Officer**  
Louise E. Magruder

- 8:00 – 8:15 a.m.**      **Opening Remarks – Introduction**
- FDA Speakers:**
- 8:15 – 8:30**            **Overview and Recap of Previous Day**  
Tremel Faison, MS, RAC, SCT(ASCP)  
Scientific Reviewer  
FDA/CDRH/OIVD/DIHD
- 8:30 - 9:00 p.m.**    **History and Lessons from FDA Regulation of Digital Radiology**  
Kyle Myers, Ph.D.  
Division Director  
FDA/CDRH/OSEL/DIAM
- 9:00 – 9:50 a.m.**    **Statistical Considerations in the Evaluation of Digital Pathology Devices**  
Shanti Gomatam, Ph.D.  
Mathematical Statistician  
FDA/CDRH/OSB/DBS
- 9:50 - 10:05 a.m.**                            **Break**
- 10:05 - 10:55 a.m.**    **Evaluation of Reader Performance and Variability**  
Brandon Gallas, Ph.D.  
Mathematician  
FDA/CDRH/OSEL/DIAM
- 10:55 - 11:45 a.m.**    **Clinical Trial Design for Digital Pathology Devices**  
Tan Nguyen, M.D., Ph.D, RAC  
Medical Officer/Pathologist  
FDA/CDRH/OIVD/DCTD
- 11:45 – 12:00 p.m.**    **Questions from the Panel for FDA Speakers**
- 12: 00 – 1:00 p.m.**                            **Lunch**
- 1:00 – 2:00 p.m.**      **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. The Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

**2:00 – 3:15 p.m.**      **Display of FDA Questions with Panel Discussion and Recommendations**

**3:15 – 3:30 p.m.**                            **Break**

**3:30 – 5:00 p.m.**      **Continuation of FDA Questions with Panel Discussion and Recommendations**

**Adjournment**

## HEMATOLOGY AND PATHOLOGY DEVICES PANEL

October 22-23, 2009

### **CHAIRPERSON**

Dorothy M. Adcock, M.D.  
Medical and Laboratory Director  
Esoterix Laboratory  
Englewood, Colorado 80112

Claudia Mello-Thoms, Ph.D.  
Research Assistant Professor  
Department of Biomedical Informatics  
UPMC Shadyside Hospital, Cancer Pavilion  
Pittsburgh, PA 15232

### **VOTING MEMBER**

Piotr Kulesza, M.D., Ph.D.  
Assistant Professor of Pathology  
Feinberg School of Medicine  
Northwestern University  
Chicago, IL 60611

Diane D. Davey, M.D.  
Professor of Pathology  
University of Central Florida  
College of Medicine  
Orlando, FL 32816

### **TEMPORARY VOTING MEMBERS**

George G. Birdsong, M.D.  
Director of Anatomic Pathology  
Grady Health Systems  
Atlanta, GA 30303

Xiao-Hua Andrew Zhou, Ph.D.  
Professor, Dept. of Biostatistics  
School of Public Health  
University of Washington  
Seattle, WA 98195-7232

Stephen M. Hewitt, M.D., Ph.D.  
Clinical Investigator, PHS, CC  
Laboratory of Pathology  
National Cancer Institute  
Bethesda, MD 20854

### **CONSUMER REPRESENTATIVE**

Pat Furlong, President and CEO  
Parent Project Muscular Dystrophy  
Middletown, OH 45042

John H. Sinard, M.D., Ph.D.  
Professor of Pathology  
Yale University School of Medicine  
New Haven, CN 06473

### **INDUSTRY REPRESENTATIVE**

Dan Bracco  
Vice President, Clinical, Quality and  
Regulatory  
Constitution Medical Inc.  
Westford, MA 01886

John R. Gilbertson, M.D.  
Associate Chief of Pathology  
Massachusetts General Hospital  
Boston, MA 02114

### **DESIGNATED FEDERAL OFFICER**

Louise E. Magruder  
Center for Devices & Radiological Health  
Food and Drug Administration  
Silver Spring, MD 20993

David J. Foran, Ph.D.  
Professor of Pathology, Laboratory Medicine  
UMDNJ – Robert Wood Johnson Med. School  
Piscataway, NJ 08854

**GUEST SPEAKERS**

Ulysses G. Balis, M.D.

Associate Professor & Director, Division  
of Pathology Informatics  
University of Michigan Health Systems  
Ann Arbor, MI 48109

Michael J. Becich, MD., Ph.D.

Chairman & Professor of Biomedical  
Informatics and Pathology  
University of Pittsburgh School of Medicine  
Pittsburgh, PA 15232

Michael R. Descour, Ph.D.

Associate Professor  
College of Optical Sciences,  
University of Arizona  
Tucson, AZ 85721

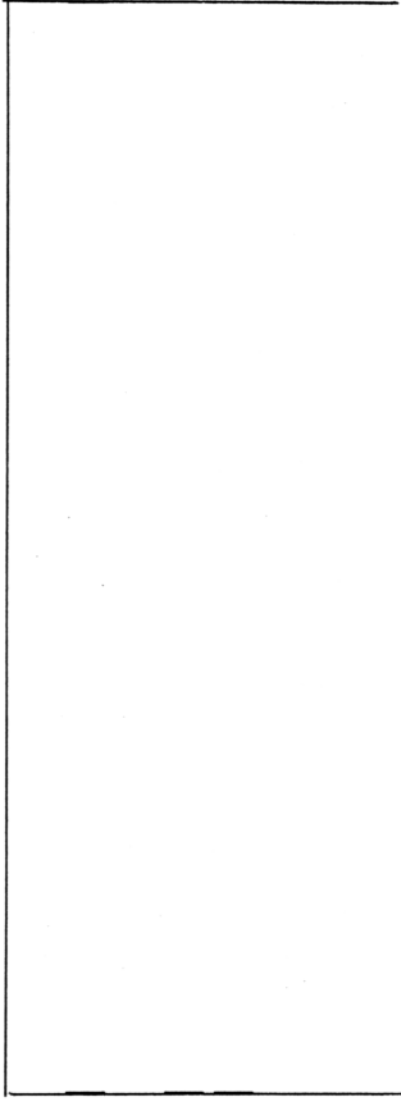
**October 22-23, 2009 Hematology/Pathology Devices Panel Meeting**

Zhou/Hewitt / Sinar/ Adcock/ Magruder/Gilbertson/Mello-Thomas

Birdsong

Davey

Bracco



Kulesza

Foran

Becker.

- Please remember to sign in and pick up meeting material at the FDA sign-in desk outside the meeting room.
- To protect any confidential material, please do not approach the panel seating area throughout the meeting (including break and lunch times). No one is allowed beyond the first row of the public seating section while the meeting is in session.
- There is no use of any flash photography or TV camera lights while the meeting is in session.
- FDA Office of Public Affairs contacts: Siobhan DeLancey (202)510-4177, Siobhan.delancey@fda.hhs.gov. and Mary (Pepper) Long (240)276-3915 mary.long@fda.hhs.gov
- A summary of this meeting will be available on FDA's Web site ([www.fda.gov](http://www.fda.gov)) within 48 hours after the end of the meeting.