

**GENERAL HOSPITAL AND PERSONAL USE DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE**

*Thirty Fifth Meeting
Hilton Washington, DC North, 620 Perry Parkway, Gaithersburg, MD
August 9, 2005*

Panel Chairperson

Secretary

Charles E. Edmiston Jr., Ph.D.
USPHS

Executive

Scott A. Colburn BSN, RN, LT,

- 8:00 a.m. **CALL TO ORDER***
- 8:00 a.m. **Welcome and Introductory Remarks**
- Charles E. Edmiston Jr., Ph.D., Chairman
 - Scott A. Colburn, BSN, RN, LT, USPHS, Executive Secretary
 - Panel Member Introductions
 - Conflict of Interest Statement
- 8:15 a.m. **Condition of Approval Studies: Recent Changes in CDRH**
- Susan Gardner, PhD
- 8:30 a.m. **Division/Branch Update**
- Chiu Lin, PhD– DAGID Division Director
 - Sheila Murphey, MD – Chief, Infection Control Devices Branch
 - Anthony D. Watson, MS, MBA – Chief, General Hospital Devices Branch
- 8:45 a.m. **Open Public Session****
- 9:15 p.m. **Presentations by FDA**
- Introduction and Welcome,
Anthony D. Watson, MS, MBA
 - Jason F. Lipman
 - Shewit Bezabeh, MD, MPH
 - Dayawansa “Daya” G. Ranamukha-arachchi, PhD.
- 10:15 a.m. **BREAK**
- 10:30 a.m. **Presentations by CDC and WHO**
- CDC - Bruce Weniger, MD, MPH, CAPT, USPHS
 - WHO – Martin Freide, PhD
- 11:30 a.m. **LUNCH BREAK**
- 12:30 p.m. **Presentations by the Industry**
- 1:30 p.m. **Panel Deliberations**
- 3:00 p.m. **BREAK**
- 3:15 p.m. **Open Public Session ****
- 3:45 p.m. **Panel Recommendations**
- 4:00 p.m. **MEETING ADJOURNED**

- * This meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson.
- ** Public attendees, who have contacted the Executive Secretary prior to the meeting, will address the Panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with the issues being discussed or with their competitors.