

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

*Thirty Sixth Meeting
Hilton Washington, DC North, 620 Perry Parkway, Gaithersburg, MD
September 27, 2005*

DRAFT

Panel Chairperson

Charles E. Edmiston Jr., Ph.D.

Executive Secretary

Scott A. Colburn, BSN, LT, USPHS

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, LT, USPHS, Executive Secretary
- Panel Introductions
- Conflict of Interest Statement

8:15 a.m. **The Challenges and Opportunities on the Critical Path to New Medical Devices**

- Sousan S. Altaie, PhD

8:30 a.m. **Division/Branch Update** - Chiu Lin, Director, PhD – DAGID Director

8:45 a.m. **Presentations by FDA**

- Sheila Murphey, MD
- Elaine Mayhall Ph.D.
- Estelle Russek-Cohen, Ph.D.
- Ronald Brown MS, DABT

10:15 a.m. **BREAK**

10:30 a.m. **FDA Guest Speaker** - Allan Hilderly
Medicines & Healthcare Products Regulatory Agency (Devices),
Device Technology & Safety-Biologics & Implants, United Kingdom

11:00 a.m. **Open Public Session***

12:00 a.m. **LUNCH BREAK**

1:00 p.m. **Presentations by Industry**

2:30 p.m. **BREAK**

2:45 p.m. **Open Public Session****

3:15 p.m. **Panel Deliberations**

4:45 p.m. **Panel Final Remarks**

5:00 p.m. **MEETING ADJOURNED**

- ** This portion of the 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 product being discussed or with their competitors.*