

Draft Meeting Agenda

GENERAL AND PLASTIC SURGERY DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE

Salons A, B & C Hilton Washington, DC North
620 Perry Parkway
Gaithersburg, Maryland
August 25 & 26, 2005

Acting Panel Chair:
Joseph LoCicero, III, M.D.

Executive Secretary:
David Krause, Ph.D.

August 25, 2005 Schedule:

- 8:00 am** **Call to Order, Conflict of Interest, Temporary Voting Member Deputization and Opening Remarks**
David Krause
- Panel Introductions**
Joseph LoCicero, III
- Panel Update**
CDR Stephen P. Rhodes, USPHS, Division of General, Restorative, and Neurological Devices (DGRND), Office of Device Evaluation (ODE)
- 8:15 am** **Critical Path Initiative in Medical Devices**
Sousan S. Altaie, Ph.D., Scientific Policy Advisor, Office of *In Vitro* Diagnostic Device Evaluation and Safety
- 8:30 am** **Condition of Approval Studies: Recent Changes in CDRH**
Susan N. Gardner, Ph.D., Director, Office of Surveillance and Biometrics
- 8:45 am** **Introduction to Device Classification**
Ms. Marjorie G. Shulman, ODE
- 9:00 am** **Classification of Bone Wax**
- Industry Presentation**
- FDA Presentation**
David Krause, PRSB, DGRND, ODE
- Panel Discussion and Address FDA Questions**
- 10:15 am** **Break**
- 10:30 am** **Open Public Comment**

11:00 am **Classification Questionnaire and Vote**
Ms. Marjorie G. Shulman, ODE

11:45 am **Lunch**

12:30 pm **Classification of Medical Maggots**

Industry Presentation

FDA Presentation
Charles N. Durfor, Ph.D., PRSB, DGRND, ODE

Panel Discussion and Address FDA Questions

1:45 pm **Open Public Comment**

2:15 pm **Classification Questionnaire and Vote**
Marjorie G. Shulman

3:00 pm **Break**

3:15 pm **Classification of Medicinal Leeches**

Industry Presentation

FDA Presentation
Charles N. Durfor

4:30 pm **Open Public Comment**

5:00 pm **Classification Questionnaire and Vote**
Marjorie G. Shulman

6:00 pm **Adjournment Day 1 Activities**

August 26, 2005 Schedule:

- 8:00 am** **Call to Order, Conflict of Interest, Temporary Voting Member Deputization and Opening Remarks**
David Krause
- Panel Introductions**
Joseph LoCicero, III
- 8:30 am** **Classification of Inflatable Tissue Expanders**
- Industry Presentation**
- FDA Presentation**
Nada O. Hanafi, MSE, PRSB, DGRND, ODE
- 9:45 am** **Open Public Comment**
- 10:15 am** **Break**
- 10:30 am** **Classification Questionnaire and Vote**
Marjorie G. Shulman
- 11:30 am** **Lunch**
- 12:30 pm** **Classification of Wound Dressing with Drugs**
- Industry Presentation**
- FDA Presentation**
Sam Arepalli, Ph.D., PRSB, DGRND, ODE
- 1:45 pm** **Open Public Comment**
- 2:15 pm** **Classification Questionnaire and Vote**
Marjorie G. Shulman
- 3:15 pm** **Meeting Adjournment and Final Remarks**
Joseph LoCicero, III