

Meeting Agenda

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

Gaithersburg Holiday Inn, Walker/Whetstone Rooms
Two Montgomery Village Avenue
Gaithersburg, Maryland
August 24 & 25, 2006

Panel Chairman:
Joseph LoCicero, III, M.D.

Executive Secretary:
David Krause, Ph.D.

August 24, 2006 Schedule:

- 8:00 am** **Call to Order, Conflict of Interest, Temporary Voting Member Deputization and Opening Remarks**
David Krause, Plastic & Reconstructive Surgery Branch (PRSB), Division of General, Restorative & Neurological Devices (DGRND), Office of Device Evaluation (ODE)
- Panel Introductions**
Joseph LoCicero, III
- Panel Update**
CAPT Stephen P. Rhodes, USPHS, Branch Chief, PRSB, DGRND, ODE
- 8:15 am** **Open Public Comment**
- 8:45 am** **BioForm Medical, Inc. Radiesse for the Treatment of HIV Associated Facial Lipoatrophy**
Stephen L. Basta, President and CEO
- Stacey L. Silvers, M.D., Ear, Nose and Throat and Facial Plastic Surgery, New York, NY
- Marc Liebeskind, M.D., J.D., Park Avenue Radiologists, PC, New York, NY
- Alastair Carruthers, FRCPC, Clinical Professor, Department of Dermatology, University of British Columbia, Vancouver, BC, Canada
- 10:15 am** **Break**
- 10:30 am** **FDA Presentation**
Herbert P. Lerner, M.D., PRSB, DGRND, ODE
- 11:00 am** **Panel Deliberations and Address FDA Questions**
- 11:45 am** **Open Public Comment**
- 12:15 pm** **Lunch**
- 1:00 pm** **FDA and Sponsor Summations, Concluding Panel Deliberations and Vote**

- 2:00 pm** **Open Public Comment**
- 2:30 pm** **BioForm Medical, Inc. Radiesse for the Treatment of Nasolabial Folds**
Steven L. Basta
- Lawrence S. Bass, M.D., F.A.C.S., Clinical Assistant Professor of Plastic Surgery, NYU
School of Medicine, New York, NY
- Marc Liebeskind
- Alastair Carruthers
- 3:45 pm** **Break**
- 4:00 pm** **FDA Presentation**
Herbert P. Lerner
- Pablo E. Bonangelino, Ph.D., General Surgery Devices Branch (GSDB), Division of
Biostatistics (DBS), Office of Surveillance and Biometrics (OSB)
- 4:45 pm** **Panel Deliberations and Address FDA Questions**
- 5:15 pm** **Open Public Comment**
- 5:45 pm** **FDA and Sponsor Summations, Concluding Panel Deliberations and Vote**
- 6:30 pm** **Adjournment of Day 1**
Joseph LoCicero, III

August 25, 2006 Schedule:

- 8:00 am** **Device Classification/Reclassification Training**
Marjorie G. Shulman, ODE
- 9:00 am** **Closed Session**
- 9:30 am** **Call to Order, Conflict of Interest, Temporary Voting Member Deputization and Opening Remarks**
David Krause
- Panel Introductions**
Joseph LoCicero, III
- 9:45 am** **Reclassification Overview**
Marjorie G. Shulman
- 10:00 am** **Reclassification of Cyanoacrylate Tissue Adhesives**
- Petitioner Presentation:**
Tierney Norsted, Ph.D., M.P.H., Executive Vice President & Sr. Principal Advisor,
Regulatory & Clinical Research Institute, Inc.
- Richard Stenton, Technical Director, MedLogic Global, Ltd.,
- Judd E. Hollander, M.D., Professor & Clinical Research Director, Department of
Emergency Medicine, University of Pennsylvania
- Ian Askill, Ph.D., President, Aspire Biotech, Inc.
- 10:30 am** **FDA Presentation:**
George Mattamal, PhD, GSDB, DGRND, ODE
- 10:45 am** **Break**
- 11:00 am** **Industry Presentations:**
- United States Surgical (Division of Tyco Healthcare Group LP)**
Philip M. Steinborn, Vice President, Regulatory & Clinical Affairs
- Kenneth N. Broadley, Ph.D., Manager, Product Development, Henkel Ireland Limited
- Closure Medical Corporation**
W. Thomas Stephens, Director, Regulatory Affairs
- 11:30 am** **Open Public Comment**
- 12:30 pm** **Lunch**
- 1:30 pm** **Panel Discussion and Address FDA Questions**
- 2:30 pm** **Classification Questionnaire and Vote**
Marjorie G. Shulman

5:00 pm

Meeting Adjournment and Final Remarks
Joseph LoCicero, III