

AGENDA

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

Grand Ballroom, Hilton Washington DC North/Gaithersburg
620 Perry Parkway, Gaithersburg, Maryland
April 11-13, 2005

Panel Chair:
Michael Choti, M.D.

Executive Secretary:
David Krause, Ph.D.

April 11, 2005

8:00 am	Call to Order
	Conflict of Interest and Opening Remarks David Krause, Ph.D., Executive Secretary
	Panel Introductions Michael Choti, M.D., Chairman
	Panel Update CDR Stephen P. Rhodes, USPHS, Acting Deputy Director, Division of General, Restorative, and Neurological Devices (DGRND), Office of Device Evaluation (ODE)
	Welcoming Remarks Miriam Provost, Ph.D., Acting Director, DGRND, ODE
8:15 am	Open Public Comment
10:15 am	Break
10:30 am	Open Public Comment Continued
12:30 pm	Lunch
1:30 pm	Open Public Comment Continued
3:30 pm	Break
3:45 pm	Open Public Comment Continued
6:30 pm	Break
7:30 pm	Open Public Comment Continued
~11:00 pm	Adjournment Day 1

April 12, 2005

8:00 am	Call to Order
	Panel Introductions Michael Choti, M.D., Chairman
8:15-9:15 am	Applicant Presentation, Inamed Corporation, Silicone-Filled Breast Implants
	Introduction Dan Cohen, Vice President of Global Government and Corporate Affairs
	Preclinical Studies Overview and Clinical Studies Overview Patricia Walker, M.D., Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer (CSO)
	Closing Remarks Scott Spear, M.D., Professor and Chief, Division of Plastic Surgery, Georgetown University Hospital; President of the American Society of Plastic Surgeons (ASPS); consultant to Inamed
9:15-9:45 am	Panel Questions to Inamed Presenters
9:45 am	Break
9:45-10:45 am	FDA Presentation
	Introduction, Device Description, and Preclinical Testing Overview CDR Samie Allen, DGRND, ODE
	Rupture Overview Sahar M. Dawisha, M.D., DGRND, ODE
	Long-Term Probability of Rupture Pablo Bonangelino, Ph.D., Division of Biostatistics, Office of Surveillance and Biometrics (OSB)
10:45-11:15 am	Panel Questions to FDA Presenters
11:15 am	Open Panel Discussion and FDA Questions
12:00 pm	Lunch
12:45 pm	Open Panel Discussion and FDA Questions Continued
2:30 pm	Break
2:45 pm	Open Public Comment
3:45 pm	FDA Summation
	Sponsor Summation
	Concluding Panel Deliberations and Vote
6:00 pm	Adjournment Day 2

April 13, 2005

8:00 am

Call to Order

Panel Introductions

Michael Choti, M.D., Chairman

8:15-9:45 am

Applicant Presentation, Mentor Corporation, Silicone Gel-Filled Breast Implants

Introduction

Josh Levine, President and CEO

Preclinical Summary

Jerry Barber, Ph.D. Vice President Corporate Research

Clinical Safety

Bruce Cunningham, M.D., Professor and Chair, Dept of Plastic Surgery, University of Minnesota

Clinical Effectiveness and Benefits

Rebecca Anderson, Ph.D. Associate Professor/Psychologist, Medical College of Minnesota

Summation

Bruce Cunningham, M.D., Professor and Chair, Dept of Plastic Surgery, University of Minnesota

9:45-10:15 am

Panel Questions to Mentor Presenters

10:15 am

Break

10:30 am-12:00 pm

FDA Presentation

Introduction, Device Description, and Preclinical Testing Overview

CDR Samie Allen, DGRND, ODE

Chemical Data Overview

Sam Arepalli, Ph.D., DGRND, ODE

Toxicological Data Overview

David B. Berkowitz, Ph.D, V.M.D., DGRND, ODE

Clinical Data Overview

Herbert Lerner, M.D., DGRND, ODE

Rupture Overview

Sahar M. Dawisha, M.D., DGRND, ODE

Statistical Overview

Phyllis Silverman, M.S., Division of Biostatistics, OSB

12:00-12:30 pm

Panel Questions to FDA Presenters

12:30 pm

Lunch

1:15 pm	Open Panel Discussion and FDA Questions
2:30 pm	Break
2:45 pm	Open Public Comment
3:45 pm	FDA Summation
	Sponsor Summation
	Concluding Panel Deliberations and Vote
6:00 pm	Concluding Remarks and Meeting Adjournment Michael Choti, MD, Chairman