

## Meeting Agenda

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

Ballroom Salons A, B, C, and D, Gaithersburg Hilton Hotel  
620 Perry Parkway  
Gaithersburg, Maryland  
March 25, 2004

**Panel Chairman:**  
Michael Choti, MD

**Executive Secretary:**  
David Krause, PhD

**8:00 am**

**Call to Order**

**Conflict of Interest, Temporary Voting Member Deputization and Opening Remarks**  
David Krause, PhD, Executive Secretary

**Panel Introductions**  
Michael Choti, MD, Chairman

**Update Since Last Meeting**  
CDR Stephen Rhodes, Branch Chief, Plastic and Reconstructive Surgery Devices Branch

**8:15 am**

**Open Public Comment**

**9:15 am**

**Applicant Presentation, Dermik Laboratories, Sculptra**

**Product History**  
Kimberley Forbes-McKean, Ph.D., Senior Director, Product Development and Commercialization - Dermik Laboratories

**Lipoatrophy Condition**  
Marcus A. Conant, M.D., Medical Director - Dermatology/HIV Consultations

**Non-clinical Data**  
Jeffrey Handler, Ph.D. DABT, Director, Drug Safety Assessment and Evaluation - Dermik Laboratories

**Clinical Data**  
Sharon Levy, M.D., Senior Medical Director, Scientific and Medical Affairs - Dermik Laboratories

**Sponsor-Investigator Studies**  
Peter Engelhard, D.O., Medical Director - Apex South Beach

**Conclusions**  
Kimberley Forbes-McKean, Ph.D. Senior Director, Product Development and Commercialization - Dermik Laboratories

**10:30 am**      **Break**

**11:00 am**      **FDA Presentation**  
Office of Device Evaluation/Division of General, Restorative & Neurological Devices

**Introduction**  
Herbert P. Lerner, MD

**Toxicology**  
David B. Berkowitz, PhD, VMD

**Clinical**  
Herbert P. Lerner, MD

**12:00 pm**      **Panel Deliberations and Address FDA Questions**

**12:30 pm**      **Lunch**

**1:30 pm**      **Continue Panel Deliberations and FDA Question Discussion:**

**2:15 pm**      **Open Public Comment**

**3:15 pm**      **Break**

**3:30 pm**      **FDA and Sponsor Summations, Concluding Panel Deliberations and Vote**

**5:00 pm**      **Adjournment**