

ORTHOPEDIC AND REHABILITATION DEVICES PANEL

Hilton Washington DC North

620 Perry Parkway

Gaithersburg, Maryland

September 8, 2005

Panel Chairperson

John S. Kirkpatrick, M.D.

Executive Secretary

Janet L. Scudiero, M.S.

- 8:30 am Call to Order**
Panel Introductions
Conflict of Interest and Deputization to Voting Member Status Statements
Postmarket Study Design
Susan N. Gardner, Ph.D., Director, Office of Surveillance and Biometrics
Update since the August 31, 2004 Meeting
Glenn A. Stiegman, Chief, Orthopedic Devices Branch

Smith and Nephew, Birmingham Hip Resurfacing (BHR) System, P040033

- 9:15 am 1st Open Public Hearing***
Orthopaedic Surgical Manufacturers' Association, Susan Krasny
Wright Medical Technology, Inc., William Maloney, M.D
- 9:45 am Sponsor Presentation**
Marcos Velez-Duran, VP Clinical/Regulatory Affairs and Quality (Trauma)
Derek J.W. McMinn, FRCS, Orthopaedic Surgeon, Birmingham Nuffield Hospital
Tim Band, Director Product Development
George DeMuth, Statistical Consultant
Neal Defibaugh, Director Clinical Affairs
- 10:45 pm Break**
- 11:00 am FDA Presentation**
John S. Goode, M.S., Orthopedic Devices Branch
Chang S. Lao, Ph.D., Division of Biostatistics, Office of Surveillance and Biometrics
- 12:00 am Lunch**
- 1:00 pm Panel Deliberations and FDA Questions**
Lead Discussant, Jay D. Mabrey, M.D.
- 3:30 pm 2nd Open Public Hearing***
- 4:00 pm Break**
- 4:15 pm FDA and Sponsor Summations**
- 4:45 pm Panel Vote**
- 6:00 pm Adjournment**

* **Open Public Hearings** - Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them.

The Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.