

**Food and Drug Administration  
Center for Biologics Evaluation and Research  
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE  
Meeting #37, March 18-19, 2004  
Hilton Hotel, Silver Spring, Maryland**

**AGENDA**

**Thursday, March 18, 2004**

- 8:30 a.m.** Call to Order/Introduction of Committee  
Mahendra Rao, M.D., Ph.D., Chair
- 8:40** Conflict of Interest Statement  
Gail Dapolito, Executive Secretary
- 8:45** FDA Opening Remarks  
Presentation of Certificates of Appreciation to Retiring Members  
Jesse Goodman, M.D., M.P.H., Director  
Center for Biologics Evaluation and Research (CBER), FDA  
  
Philip Noguchi, M.D., Acting Director  
Office of Cellular, Tissue and Gene Therapies, CBER
- 9:00** **Open Committee Discussion – Cellular Therapies for Cardiac Disease**  
FDA Introduction and Perspectives  
Dwayne Rieves, M.D., Chief 4018sl - 01  
Clinical Evaluation Branch  
Office of Cellular, Tissue and Gene Therapies, CBER
- Guest Presentations:
- 9:30** Overview Cardiomyopathy and Ischemic Heart Disease  
Emerson Perin, M.D., Ph.D., Director  
New Cardiovascular Interventional Technology  
Texas Heart Institute
- 10:00** Q&A
- 10:10** Break
- 10:25** Clinical Experience of Autologous Myoblast Transplantation  
Philippe Menasché, M.D., Professor  
Thoracic and Cardiovascular Surgery  
University of Paris
- 10:55** Q&A
- 11:05** Bone Marrow Cell Therapy For Angiogenesis: Present and Future  
Steven Epstein, M.D., Executive Director  
Cardiovascular Research Institute  
Washington Hospital Center
- 11:35** Q&A
- 11:45 a.m.** Lunch

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- Open Committee Discussion – Cellular Therapies for Cardiac Disease**
- 12:45 p.m.** Cellular Therapies for Cardiac Diseases – FDA Preclinical Perspective *401851-01*  
Richard McFarland, Ph.D., M.D., Medical Officer  
Pharmacology/Toxicology Branch  
Office of Cellular, Tissue and Gene Therapies, CBER
- Guest Presentations:
- 1:05** Myoblasts: The First Generation Cells for Cardiac Repair -  
What Have We Learned?  
Doris Taylor, Ph.D., Professor  
Department of Physiology  
University of Minnesota
- 1:35** Q&A
- 1:45** Preclinical Models - Hematopoietic and Mesenchymal Cell  
Therapies for Cardiac Diseases  
Silviu Itescu, M.D., Associate Professor of Medicine and Surgery  
Division of Surgical Science  
Columbia University Medical Center
- 2:15** Q&A
- 2:25** From Mouse to Man: Is it a Logical Step for Cardiac Repair?  
Doris Taylor, Ph.D.  
University of Minnesota
- 2:55** Q&A
- 3:05** Break
- 3:15** Cardiac Catheters for Delivery of Cell Suspensions *401851-09*  
Donald Nick Jensen, D.V.M., M.S.E.E.  
Electrical Engineer  
Office of Device Evaluation  
Center for Devices and Radiological Health, FDA
- 3:35** Q&A
- 3:45** Transcatheter Myocardial Cell Delivery: Questions and *401851-10*  
Considerations from the Trenches  
Robert Lederman, M.D., Investigator  
Cardiovascular Branch  
National Heart, Lung and Blood Institute, NIH
- 4:05** Q&A
- 4:15** Open Public Hearing
- 4:45 p.m.** Adjourn

