

**Food and Drug Administration
Center for Biologics Evaluation and Research
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
Meeting # 36
Holiday Inn, Gaithersburg, MD
October 9-10, 2003**

AGENDA

Thursday October 9, 2003

Session 1: Allogeneic Islet Transplantation

- 8:00 a.m.** Opening and Introduction of Committee
Dr. Mahendra Rao, Acting Chair, BRMAC
- 8:10** Conflict of Interest Meeting Statement
Gail Dapolito, Executive Secretary, BRMAC
- 8:15** FDA Introduction
Dr. Philip Noguchi
Acting Director, Office of Cellular, Tissue and Gene Therapies (OCTGT)
Center for Biologics Evaluation and Research, FDA

Dr. Jesse Goodman
Director
Center for Biologics Evaluation and Research, FDA
- 8:35** Federal Oversight of Allogeneic Islet Transplantation
Overview of FDA Regulatory Issues
Dr. Darin Weber
Chief, Cell Therapy Branch, Division of Cellular and Gene Therapies (DCGT)
Center for Biologics Evaluation and Research, FDA
- 8:45** HRSA's Role in Pancreas and Islet Transplantation
Dr. Jim Burdick
Director, Division of Transplantation
Office of Special Programs
Health Resources and Services Administration
- 9:05** Moving from Investigational Islet Products to Licensed Islet Products
Expectations for Facilities & cGMPs
Dr. Nicholas Obiri
Microbiologist, Division of Compliance and Biologics Quality
Center for Biologics Evaluation and Research, FDA
- 9:25** Processing and Product Quality Issues, Assessing the Final Product
Dr. Keith Wonnacott
Microbiologist, Cell Therapy Branch, DCGT
Center for Biologics Evaluation and Research, FDA
- 9:45** Q&A
- 10:05 a.m.** Break

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AGENDA (cont'd)

Thursday October 9, 2003

Session 1: Allogeneic Islet Transplantation (Cont'd)

- 10:20 a.m.** FDA Introduction to Guest Presentations
Dr. Darin Weber
Chief, Cell Therapy Branch, DCGT
Center for Biologics Evaluation and Research, FDA
- 10:30** Islet Processing: Evolution and Current Standards
Dr. Camillo Ricordi
Professor of Surgery, Department of Surgery
University of Miami
- 10:55** Q&A
- 11:10** Current Status of Islet Characterization and Quality
Dr. Bernhard Hering
Associate Professor of Surgery, Department of Surgery
University of Minnesota
- 11:35** Q&A
- 11:50** Open Public Hearing
- 12:20 p.m.** Lunch
- 1:30** Committee Discussion of Questions
- 3:00** Break
- 3:15** Committee Discussion of Questions (cont'd)

Session 2: Update of Research Programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins

- 4:15** Introduction – Laboratory of Stem Cell Biology and Laboratory of Immunology and Virology, Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapies
Dr. Raj Puri
Acting Director, DCGT, OCTGT
Center for Biologics Evaluation and Research
- 4:20** Laboratory of Immunology and Virology
Dr. Carolyn Wilson
Senior Investigator, Laboratory of Immunology and Virology (LIV), DCGT
- 4:30** Dr. Andrew Byrnes
Senior Staff Fellow, LIV, DCGT
- 4:35 p.m.** Dr. Nancy Markovitz
Senior Staff Fellow, LIV, DCGT

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AGENDA (cont'd)

Thursday October 9, 2003

**Session 2: Update of Research Programs in the Division of Cellular and Gene Therapies
and the Division of Therapeutic Proteins**

- 4:40 p.m.** Laboratory of Stem Cell Biology
 Dr. Steven Bauer
 Acting Chief, Laboratory of Stem Cell Biology, DCGT
 Center for Biologics Evaluation and Research, FDA
- 4:45** Introduction – Laboratory of Biochemistry, Division of Therapeutic Proteins,
 Office of Biotechnology Products
 Dr. Amy Rosenberg
 Director, Division of Therapeutic Proteins
 Office of Biotechnology Products
 Center for Drugs Evaluation and Research, FDA
- 4:50** Laboratory of Biochemistry
 Dr. Emily Shacter
 Chief, Laboratory of Biochemistry
- 4:55** Break
- Closed Session**
- 5:50 p.m.** Adjourn

