

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESEARCH REVIEW SUBCOMMITTEE OF THE
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE**

**SITE VISIT
OFFICE OF CELLULAR, TISSUE AND GENE THERAPIES**

**September 29, 2005
Holiday Inn Select, Bethesda, MD**

DRAFT AGENDA

Open Committee Discussion

- 8:00 a.m.** Welcome and Introduction of Committee
Mahendra Rao, M.D., Ph.D., Chair
- 8:10** Conflict of Interest Statement
Gail Dapolito, Executive Secretary
- 8:15** Introduction/Charge to Committee
Jesse L. Goodman, M.D., M.P.H.
Director, Center for Biologics Evaluation and Research
CBER Mission
CBER Program Structure
- 8:40** Overview of CBER Research Programs
Kathryn Carbone, M.D.
Associate Director for Research
- 9:10** Overview of the Office of Cellular, Tissue and Gene Therapies (OCTGT)
Celia Witten, M.D., Director
Office Mission and Structure
Regulatory Activities and Priorities
Research Program Introduction
- 9:35** Q & A
- 9:50 a.m.** Break

**Research Review Subcommittee of the
Cellular, Tissue and Gene Therapies Advisory Committee
Site Visit Review
Office of Cellular, Tissue and Gene Therapies
September 29, 2005**

DRAFT AGENDA (Cont'd)

Open Committee Discussion

- 10:05 a.m.** Overview of the Division of Cellular, Tissue and Gene Therapies (DCGT)
Raj Puri, M.D., Ph.D., Director DCGT
Mission/Philosophy/Regulatory Activities and
Public Health Impact
Regulatory and Research Expertise
Research Program Structure and Research
Activities and Priorities
- 10:40** Office of Cellular, Tissue and Gene Therapies Research Program
Suzanne Epstein, Ph.D., Associate Director of Research, OCTGT
Research Management, Accomplishments and Future Plans
- 11:05** Q&A
- 11:20** **Open Public Hearing**
- 12:20 p.m.** Adjourn Open Session
- 1:20** **Closed Committee Discussion**
- 4:00 p.m.** Adjourn Closed Session
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