

FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE
Meeting #44, Teleconference
July 26, 2007
National Institutes of Health, Building 29B, Conference Rooms A/B
Bethesda, Maryland

DRAFT AGENDA

OPEN SESSION

11:00 a.m. Eastern Time

Opening Remarks

Walter Urba, M.D., Ph.D., Acting Chair

Roll-Call and Conflict of Interest Statement

Gail Dapolito, Executive Secretary

11:10

Introduction – Site Visit Process

Kathryn Carbone, M.D., Associate Director for Research
Center for Biologics Evaluation and Research

11:30

Overview of Research Program – Office of Cellular, Tissue and Gene
Therapies (OCTGT)

Celia Witten, M.D., Ph.D., Director, OCTGT

11:40

Overview of Research – Gene Transfer and Immunogenicity Branch (GTIB)

Eda Bloom, Ph.D., Chief, GTIB

12:10 p.m.

Q&A

12:15

Overview of Research Program - Office of Biotechnology Products
(OBP)

Elizabeth Shores, Ph.D., Deputy Director, (OBP)

12:20

Overview of Research – Division of Monoclonal Antibodies (DMA),

Kathleen Clouse, Ph.D., Director, DMA

12:35

Q&A

12:40

Overview of Research – Division of Therapeutic Proteins (DTP), OBP

Amy Rosenberg, M.D., Director, DTP

1:10 p.m.

Q&A

1:15

Open Public Hearing

2:15

CLOSED SESSION

3:25 p.m.

Adjourn