

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE
Meeting #41
February 9-10, 2006
Hilton Hotel, Gaithersburg, MD**

February 9, 2005

OPEN SESSION

8:00 a.m. Opening Remarks and Introduction of Committee Members
 James Mulé, Ph.D., Chair

8:10 Conflict of Interest statement
 Gail Dapolito, Executive Secretary

Topic I: CTGTAC Potency Measurements for Cell and Gene Therapy Products

8:15 FDA Introduction
 Denise K. Gavin, Ph.D.
 Division of Cellular and Gene Therapies (DCGT), FDA

8:35 Q&A

Guest Presentations

8:45 John Elliott, Ph.D.,
 National Institute of Standards and Technology

9:05 Q&A

9:20 David C. Kaslow, M.D.
 Vical, Inc.

9:40 Q&A

9:55 Break

10:05 Bryan Butman, Ph.D.
 GenVec, Inc.

10:25 Q&A

10:40 Alla Danilkovitch, Ph.D.
 Osiris Therapeutics, Inc.

11:00 Q&A

11:15 Kelledy Manson, M.T., M.S.
 Therion Biologics Corp.

11:35 Q&A

11:50 Nicole Provost, Ph.D.
 Dendreon Corp.

12:10 p.m. Q&A

12:25 Lunch

1:30 Open Public Hearing

2:00 Committee Discussion of Questions

5:30 p.m. Adjourn

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February 10, 2006

OPEN SESSION

- 8:00 a.m. Opening Remarks and Introduction of Committee
 James Mulé, Ph.D., Chair
- 8:10 Recognition of Committee Service of Retiring Members
 Jesse Goodman, M.D., M.P.H., Director, CBER

**Topic II: National Toxicology Program, Proposed Study on Retroviral Vector
Insertional Mutagenesis**

- 8:25 FDA Introduction
 Carolyn A. Wilson, Ph.D., DCGT
- 8:35 Review of Relevant Data from Preclinical Studies
 Christopher Baum, M.D.
 Hannover Medical School
- 9:05 Q&A
- 9:10 NTP Study Proposal
 Richard Irwin, Ph.D.,
 National Institute of Environmental Health Sciences
- 9:40 Q&A
- 9:45 Open Public Hearing
- 10:15 Break
- 10:30 Committee Discussion of Questions

**Topic III: Overview - Research Program, Office of Cellular, Tissue and Gene
Therapies, (OCTGT) CBER**

- 11:30 CBER Research Program
 Kathryn Carbone, M.D., Deputy Director for Research, CBER
- 11:40 OCTGT Research Program
 Celia Witten, M.D., Director, OCTGT
 Suzanne Epstein, Ph.D., Associate Director for Research, OCTGT
- 12 noon Q&A
- 12:10 p.m. **CLOSED SESSION**