

**Food and Drug Administration
Center for Biologics Evaluation and Research
Cellular, Tissue and Gene Therapies Advisory Committee
March 4, 2005
Meeting #38
Quality Suites, Rockville, MD**

DRAFT AGENDA

March 4, 2005

Open Committee Discussion

Topic I - Cellular Therapies for Repair and Regeneration of Joint Surfaces

- 8:00 a.m.** Welcome and Administrative Remarks
- 8:05** Committee Discussion of Clinical Questions
- 8:30** FDA Perspective on Development of Cartilage Repair Products – Manufacturing
- 8:50** Committee Discussion of Manufacturing Questions
- 11:00** Lunch

Topic II – Update on Retroviral Vector-Mediated Insertional Tumorigenesis

- 12:00 noon** Open Public Hearing
- 12:30 p.m.** FDA Introduction
- Guest Presentations:
- 12:45** Update on Severe Adverse Event in X-SCID Gene Therapy Protocol
- 1:25** Report on a Myeloid Malignancy Arising in a Rhesus Macaque 6 Years Following Transplantation of Retrovirally-Transduced Cells
- 2:00** Update on Murine Studies with Wildtype Murine Retroviruses
- 2:30** Retroviral Vector-Mediated Insertional Mutagenesis: Insights from Mouse Models
- 2:45** Use of Retroviral Vector-Mediated Gene Transfer in ADA-SCID Clinical Trials
- 3:10** Committee Discussion of Questions
- 5:00 p.m.** **Adjourn**