Food and Drug Administration

Center for Biologics Evaluation and Research

Cellular, Tissue and Gene Therapies Advisory Committee

Meeting #38 March 3-4

Quality Suites, Rockville, MD

DRAFT AGENDA

March 3, 2005

Open Committee Discussion

Cellular Therapies for Repair and Regeneration of Joint Surfaces

8:00 a.m.	Welcoming Remarks
	Conflict of Interest Statement
	Introduction of Members Recognition of Member Committee Service
8:30	FDA Introduction
8:40	Guest Presentation: Evaluating Methods of Restoring Cartilaginous Articular Surfaces
9:10	Guest Presentation: The Biology of the Joint Surface
9:50	Break
10:00	FDA Perspective on Development of Cartilage Repair Products – Preclinical
10:20	Guest Presentation: Preclinical Models
11:00	Open Public Hearing
11:30 12:30 p.m.	Committee Discussion of Preclinical Questions Lunch
1:30 p.m.	Committee Discussion of Preclinical Questions (cont'd)
2:30	FDA Perspective on Development of Cartilage Repair Products-Clinical
2:50	Guest Presentations: Clinical Issues
4:10 H	Break
4:25 4:30 6:00 p.m.	FDA Introduction to Clinical Questions Committee Discussion of Clinical Questions Adjourn

Cellular, Tissue and Gene Therapies Advisory Committee Meeting #38 March 3-4, 2005

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 (Continued from March 3)
8:30	FDA Perspective on Development of Cartilage Repair Products – Manufacturing
8:50	Committee Discussion of Manufacturing Questions
11:00 a.m.	Adjourn