

**Biological Response Modifiers Advisory Committee
Meeting #28
November 16-17, 2000**

Bibliography

Session I

Structural Characterization of Gene Transfer Vectors

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Session II

Preclinical Models

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**Session II (Cont'd)
Preclinical Models**

Guidance for Industry - Guidance for Human Somatic Cell Therapy and Gene Therapy.
<http://www.fda.gov/cber/guidelines.htm>.

Guidance for Industry - S6 Preclinical Safety Evaluation of Biotechnology-Derived
Pharmaceuticals. <http://www.fda.gov/cber/guidelines.htm>

**Session III
Issues in Long Term Follow-up of Clinical Trial Participants**

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somatic cells. *Bone Marrow Transplant*, **9**(1), 131-138.

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**Session IV
Issues in Germ Line Transmission**

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Retroviruses in Retroviral Vector Based Gene Therapy Products and During Follow-up
of Patients in Clinical Trials Using Retroviral Vectors.
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