Food and Drug Administration
Cellular, Tissue and Gene Therapies Advisory Committee
Meeting #41, February 10, 2006

National Toxicology Program Proposed Study Design: Model for Retroviral Mediated Insertional Mutagenesis

DRAFT QUESTIONS for Committee:

1) Please comment on the general scientific approach proposed to evaluate a mouse bone marrow transplantation model for its feasibility to assess pre-clinical safety of retroviral vectors.
2) The FDA/NTP partnership may have opportunities to explore other models in the future. Please comment on future studies that may be useful to assess retroviral vector safety.
    a. Specifically, please comment on whether the use an *in utero* gene transfer model, such as that used by Themis, et al (Ref. 8), should be examined through the NTP program for its potential as a toxicology model for assessing lentivirus vector tumorigenicity.
3) If time permits, we would welcome your comments on the following:
    a. Possible toxicology models of other cellular or gene therapies that would be useful to study through the NTP.

    b. The use of NTP as a pathway for development of toxicological testing models for novel therapies.