Food and Drug Administration
Center for Biologics Evaluation and Research
Biological Response Modifiers Advisory Committee
Meeting #33, October 10, 2002

Question for the Committee:

Are there additional data or measures that clinical investigators need to provide before future and present clinical trials in SCID patients should proceed in the US? Please consider in your discussion each of the following:

a) Consideration of risk/benefit of gene therapy vs. alternative therapies;
b) Revisions to informed consent documents;
c) Alterations to the cell dose administered;
d) Alterations to the vector dose administered;
e) Mapping of vector insertion sites on all clinical lots of cells prior to release for clinical use;
f) Alterations in vector design (i.e., SIN vectors)