NIH Recombinant DNA Advisory Committee to Meet September 13-14 - The quarterly public meeting of the NIH Recombinant DNA Advisory Committee (RAC) will take place September 13-14; the preliminary agenda for the meeting is available on the OBA Web site.

The RAC will review and discuss selected human gene transfer protocols including:

- A phase I/II safety, pharmacokinetic, and pharmacodynamic study of APS001F, a Bifidobacterium longum modified to express the cytosine deaminase gene derived from E. coli, for the treatment of advanced and/or metastatic solid tumors;

- A discussion of a phase I study of Toca 511, a replication competent murine leukemia virus encoding the yeast cytosine deaminase gene, for patients with recurrent, resectable high-grade glioblastoma; and

- An update to a previously reviewed gene therapy trial for SCID-XI using a self-inactivating gammaretroviral vector.

The RAC will also hold discussions related to:

- The results of a Phase I/II randomized, double-blinded, placebo-controlled dose escalation trial of intracoronary administration of MYDICAR (AAV/SERCA2a) in subjects with heart failure;

- Proposed changes to Section III-E-1 of the NIH Guidelines for Research Involving Recombinant DNA Molecules, which addresses research with defective viral genomes in tissue culture, as well as proposed changes to Appendix B, “Classification of Human Etiologic Agents on the Basis of Hazard”; and

- Ways to facilitate IBC review of certain of certain low-risk human gene transfer protocols.

The meeting will be held at the Hilton Rockville Hotel and Executive Center, 1750 Rockville Pike, Rockville, MD 20852. All portions of the meeting are open to the public and will be webcast. Please visit the meetings page of the OBA Web site to access the link to the webcast and to obtain a copy of the complete agenda.

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