OBA News

News from the NIH Office of Biotechnology Activities
August 18, 2009
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NIH Recombinant DNA Advisory Committee to Meet September 9, 2009 - The preliminary agenda for the September 9 meeting of the NIH Recombinant DNA Advisory Committee (RAC) is now available on the OBA Web site.

On September 9, the RAC will review and discuss selected human gene transfer protocols, including a Phase I study of IL-2-expressing attenuated *Salmonella enterica* Typhimurium in patients with unresectable hepatic metastases from any non-hematologic primary cancer. Also on the agenda is a discussion of a Phase I open-label, escalating-dose study of the safety and tolerability of single daily doses of CEQ 508, an RNAi-based therapy for Familial Adenomatous Polyposis. In addition, there will be a discussion regarding a first-in-human safety and dose-finding study of a new type-16 Human Rhinovirus (RG-HRV16) inoculum in healthy volunteers.

The meeting will also feature a presentation by Dr. Daniel Takefman, Chief, Gene Therapy Branch, FDA on recent work by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use concerning “General Principles to Address Virus and Vector Shedding.”

The RAC meeting will be held at the Hilton Rockville Hotel & Executive Center, 1750 Rockville Pike, Rockville, MD 20852**.** The RAC meeting is open to the public, requires no prior registration, and will be webcast. Please visit the meetings page of the OBA Web site to access the link to the webcast.

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