

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Cell and Gene Therapy Clinical Trials in Pediatric Populations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing a public workshop entitled “Cell and Gene Therapy Clinical Trials in Pediatric Populations.” The purpose of the workshop is to gather information from Institutional Review Boards (IRBs), gene and cellular therapy clinical researchers, and other stakeholders regarding best practices related to cell and gene therapy clinical trials in pediatric populations, as well as challenges and considerations in the review of these clinical trials.

Date and Time: The public workshop will be held on November 2, 2010, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX 301-827-3079; email: CBERTraining@fda.hhs.gov (Subject line: Pediatrics Ethics Workshop).

Registration: Email, mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 1, 2010. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop will include presentations on cell and gene therapy clinical trials in pediatric populations. The workshop will include panel discussions regarding best practices related to cell and gene therapy clinical trials in pediatric populations including those related to: (1) Evaluating these novel therapeutic products prior to initiating pediatric clinical studies; (2) identifying and minimizing risks associated with the administration of cell and gene therapy products in pediatric populations; (3) obtaining informed consent and assent; and (4) conducting continuing review of cell and gene therapy products in pediatric populations. The workshop also will include panel discussions addressing the challenges and considerations in the review of cell and gene therapy clinical trials in pediatric populations and the role of IRBs.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom

of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>.

Dated: August 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 10-????? Filed ??-??-10; 8:45 am]

BILLING CODE 4160-01-S