will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Prior to the meeting, presenters will be notified of their allotted time and the approximate scheduled time of their remarks. An agenda of the public meeting, including the oral presentation schedule, will be available approximately 3 days before the public meeting at the Division of Dockets Management (Docket No. FDA–2009–D–0007) and on the Internet at *http://www.regulations.gov*.

Pre-registered participants will receive additional information on parking and public transportation with their e-mail registration confirmation.

IV. Comments on the Draft Guidance

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding the Draft Guidance. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number FDA–2009–D–0007. Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on Draft Guidance by January 5, 2011. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the meeting. 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.

Dated: September 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22198 Filed 9–3–10; 8:45 am]

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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. 2010–22168 Filed 9–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 45134–45142, dated August 2, 2010) is amended to reflect the reorganization of the Office of Health and Safety, Office of the Chief Operating Officer, Office of the Director, Centers for Disease Control and Prevention.