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 Comments on the Draft Guidance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of attendance at the public meeting, interested persons may submit either electronic or written comments regarding the Draft Guidance.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on Draft Guidance by January 5, 2011.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]

BILLING CODE 4160–01–S

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.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statements for the Office of Health and Safety (CAJP), and insert the following:

Office of Safety, Health, and Environment (CAJP). The mission of the Office of Safety, Health, and Environment (OSHE) of the Centers for Disease Control and Prevention (CDC) is to help workers protect themselves as they carry out their public health mission. By helping staff create a safe, healthful workplace environment, by assisting in the prevention of work-related injury and illness, and by promoting safe work practices, the Office improves worker morale, increases efficiency and contributes to the creation of sound public health science. In carrying out its mission, OSHE: (1) Provides leadership and service for the CDC Health and Safety Program to proactively ensure safe and healthy workplaces at CDC worksites for CDC employees, contractors, and visitors (including deployed personnel), and to protect the environment and communities adjacent to CDC-owned and leased facilities; (2) promotes healthy and safe work practices to prevent injury and illness, and provides occupational medical, employee assistance, and worksite health promotion/lifestyle services; (3) provides advice and counsel to the CDC Director and other senior OD and Centers/Institute/Offices (ClO) staff on health, safety, and environment-related matters, and to individuals and organizations nationally and internationally, as requested; (4) provides advice, counsel, and direct support services to supervisors and employees on health, safety, and environment-related matters; (5) assures compliance with applicable federal, state, and local health, safety, and environmental (HSE) laws and regulations; (6) provides liaison with both CDC safety officers and staff, and other partners such as Health and Human Services (HHS) health and safety officials, Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), and other governmental and non-governmental organizations on HSE issues; (7) coproduces the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories; (8) serves as a World Health Organization Collaborating Center for Applied Biosafety Programs and Training; (9) serves as a significant resource of subject matter expertise for the national and international community in the field of biosafety; and, (10) works with key partners, such as the World Health Organization, on critical health and safety issues around the globe.

Office of the Director (CAJP1). (1) Serves as the principal advisor to the Director, CDC, with responsibility for the CDC Health and Safety Program; (2) plans, identifies, and requests required resources; directs, manages, and evaluates the operations and programs of OSHE; (3) assures coordination and cooperation among OSHE staff; (4) provides advice and counsel to the CDC Director, the Chief Operating Officer, and other senior OD and CIO officials on workplace HSE matters; (5) assures compliance with applicable federal, state, and local HSE laws, regulations, and policies; (6) develops and implements new HSE injury/illness prevention programs indicated by surveys, incident investigations, reports of unsafe/unhealthful working conditions and other means; (7) assures cross-cutting, collaborative team functionality in building and maintaining a successful safety program; (8) assures OSHE coordination with the Office of Security and Emergency Preparedness, the Building and Facilities Office, and other staff and staff service offices on HSE matters; (9) provides liaison with both CDC safety officers and staff, and other partners such as HHS, OSHA, EPA, NRC, and other governmental and non-governmental organizations on HSE issues; (10) when asked, consults with individuals and organizations nationally and internationally on issues such as laboratory safety, biosafety, occupational health issues in the biomedical laboratory and animal care setting, and deployment health and safety; (11) maintains oversight and support for the CDC safety committees in operational components with representation, attendance, interaction and collaboration, and collaboration with non-Atlanta health and safety officers and staff and (12) provides an annual report on the CDC HSE and other 4 reports required or requested by CDC management officials, HHS, and regulatory agencies.

Dated: August 22, 2010.

William P. Nichols,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–21764 Filed 9–3–10; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Free Trade Agreements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651–0117.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning: Free Trade Agreements. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before November 8, 2010, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 7th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP