mechanisms of action. The draft guidance applies to therapeutic cancer vaccines intended to be administered to patients with an existing cancer for the purpose of treatment. It does not apply to products intended to be administered to patients to prevent or decrease the incidence of cancer. Also, it does not apply to adoptive immunotherapeutic products such as T cell or NK cell products.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 50 on informed consent have been approved under OMB control number 0910–0130.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: September 15, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22531 Filed 9–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0431]

Preparation for International Conference on Hamonization: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in St. Louis, Missouri'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in St. Louis, MO. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the public meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in St. Louis, MO, October 24 to 29, 2009, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on Wednesday, October 14, 2009, from 2:30 p.m. to 4:30 p.m.

Location: The public meeting will be held at the Washington Room at the Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mary Morrison, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *Mary.morrison@fda.hhs.gov*, or FAX: 301–827–0003.

Registration and Requests for Oral Presentations: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers), written material and requests to make oral presentations, to Mary Morrison (see *Contact Person*) by October 9, 2009.

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

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labor and Welfare, the Japanese Pharmaceutical Manufactures Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 2:30 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 9, 2009, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses,

telephone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm181849.htm*.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained 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 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22445 Filed 9–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel. Transdisciplinary Cancer Genomics Research: Post-Genome Wide Association (Post-GWA) Initiative.

Date: October 27–28, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Marvin L. Salin, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 7073, Bethesda, MD 20892–8329. 301–496–0694. *msalin@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–22568 Filed 9–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

Notice is hereby given that I have delegated to the Regional Program Managers, American Indian Alaska Native Program Branch Chief, and Migrant and Seasonal Program Branch Chief the following authority vested in me by the Director, Office of Head Start in the memorandum dated August 27, 2009.

(a) Authority Delegated:

Authority to approve or disapprove requests for non-Federal share waivers under 42 U.S.C. 9835(b) for expenditures funded by the American Recovery & Reinvestment Act of 2009, Public Law 111–5 (Feb. 17, 2009).

(b) Limitations:

1. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

2. These authorities may not be redelegated.

(c) Effective Date:

This redelegation is effective on the date of signature.

(d) Effect on Existing Delegations:

This redelegation of authority supplements the previous delegations from the Director, Division of Program Operations by the memorandum dated April 26, 2007.

I hereby affirm and ratify any actions taken by any Regional Program Manager, the American Indian Alaska Native Program Branch Chief or the Migrant and Seasonal Program Branch Chief that involved the exercise of this authority prior to the effective date of this redelegation.

Dated: August 28, 2009.

Renee Perthuis,

Director, Division of Program Operations.

[FR Doc. E9–22572 Filed 9–17–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2009–0846]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0100

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Request (ICR) and Analysis to the Office of Management and Budget (OMB) requesting an extension of its approval for the following collection of information: 1625–0100, Advanced Notice of Vessel Arrival. Before submitting this ICR to OMB, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before November 17, 2009.

ADDRESSES: To avoid duplicate submissions to the docket [USCG–2009–0846], please use only one of the following means:

(1) *Online: http://www.regulations.gov*.

(2) *Mail:* Docket Management Facility (DMF) (M–30), U.S. Department of Transportation (DOT), West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand deliver:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov*.