from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The eight ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. 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 the IFPMA, as well as observers from the World Health Organization and the European Free Trade Area.

The eCTD is an ICH standard based on specifications developed by ICH and its member parties. The ICH M2 Expert Working Group has previously developed a list of requirements for input in the eCTD RPS Project. The list of requirements was last updated on November 11, 2010, and is available at *http://estri.ich.org/ICH_eCTD_NMV_Requirements-V4-0.pdf* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

The ICH M8 Expert Working Group was formed in November 2010 to assume responsibility for the continued development of the next major version of the eCTD.

In February 2015, the ICH Steering Committee agreed that a draft guidance entitled ''M8 eCTD v4.0 Draft Implementation Guide v2.0'' and the related document entitled ''eCTD v4.0 Implementation Package Draft Specification for Submission Formats v2.0'' should be made available for public comment. These documents are the product of the M8 Expert Working Group. Comments about these draft documents will be considered by FDA and the M8 Expert Working Group.

Since adoption of the eCTD standard, the ICH Steering Committee has endorsed using the RPS Release 2 standard. A core feature of the RPS standard is the flexibility the message provides to enable future eCTD enhancements. The M8 eCTD draft implementation guidance provides instructions for creating the eCTD v4.0 RPS message for the ICH Modules 2 through 5 of the eCTD. The draft specifications document provides specifications for creating files for inclusion in the eCTD. These draft documents facilitate implementation of the eCTD v4.0 standard. The draft documents are being issued as a package that includes the draft ICH code list and the M8 schema files. In addition, the FDA regional/module 1 documents have been developed and are available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm.*

The M8 eCTD draft implementation guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding these documents to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: *April 21, 2015.*

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–09646 Filed 4–24–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: May 28–29, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: BW Plus Tuscan, a Kimpton Hotel, 425 North Point Street, San Francisco, CA 94133.

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: May 28–29, 2015.

Time: 8:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: High Throughput Screening.

Date: May 28, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nancy Templeton, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7849, Bethesda, MD 20892, 301–408–9694, *templetonns@mail.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: May 28–29, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov*.

Name of Committee: Immunology Integrated Review Group, Cellular and Molecular Immunology—B Study Section.

Date: May 28–29, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Betty Hayden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892, 301–435–1223, *haydenb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic Industrial Partnership.

Date: May 28, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Pregnancy in Women with Disabilities.

Date: May 28, 2015.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Priscah Mujuru, RN, MPH, DRPH, COHNS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *mujurup@mail.nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: May 28, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301–437–7872, *jenkinsml2@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomedical Computing and Health Informatics.

Date: May 28, 2015.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Peter J Kozel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301–435–1116, *kozelp@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 21, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09622 Filed 4–24–15; 8:45 am]

BILLING CODE 4140–01P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Institute of Nursing Research Special Emphasis Panel; Fellowship and Career Development.

Date: June 4, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 703, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: April 21, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09621 Filed 4–24–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0032]

Agency Information Collection Activities: Importers of Merchandise Subject to Actual Use Provisions

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.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Importers of Merchandise Subject to Actual Use Provisions. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before June 26, 2015 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, 90 K Street NE., 10th 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, 90 K Street NE., 10th 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