SUPPLEMENTARY INFORMATION:

I. Background

In 2003, FDA issued updated guidance on the ''replacement reagent and instrument family policy'' for in vitro diagnostic (IVD) devices. The 2003 guidance described a mechanism for manufacturers to follow when applying an assay that was previously cleared for use based on performance characteristics with a specified instrument, to an additional instrument that was previously cleared or that is a member of an instrument family from which another member has been previously cleared. Through the approach described in the 2003 guidance, manufacturers established sufficient control to maintain the level of safety and effectiveness demonstrated in the cleared device for these types of modified devices, when evaluated against predefined acceptance criteria using a proper validation protocol, without submission of a premarket notification (510(k)).

FDA believes this policy is important for public health as it promotes more timely availability of a wider array of clinical laboratory tests for patient benefit. To ensure that its full benefits are realized, FDA is providing additional clarity to help manufacturers and FDA better apply the concepts in the guidance.

This draft guidance, when finalized, is intended to update and provide clarity on the Replacement Reagent and Instrument Family Policy for manufacturers of IVD devices and FDA staff. It incorporates concepts and recommendations from FDA's guidance entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' issued on October 25, 2017 (82 FR 49375).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices. 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16045 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidances. 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 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; the collections of information in the guidance document ''Administrative Procedures for CLIA [Clinical Laboratory Improvement Amendments of 1988] Categorization'' are approved under OMB control number 0910–0607; and the collections of information for requests for feedback on medical device submissions in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: December 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27132 Filed 12–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34) and Implementation Cooperative Agreement (U01).

Date: January 16, 2018.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 12, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–27128 Filed 12–15–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Institute of Child Health and Human Development Initial Review Group; Population Sciences Subcommittee.

Date: February 9, 2017.

Time: 8:00 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: Minki Chatterji, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2121D, Bethesda, MD 20892–7501, 301–827–5435, *minki.chatterji@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Archiving and Documenting Child Health and Human Development Data Sets.

Date: February 9, 2018.

Time: 8:00 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: Minki Chatterji, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2121D, Bethesda, MD 20892–7501, 301–827–5435, *minki.chatterji@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 12, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–27129 Filed 12–15–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

The Department of Homeland Security, Stakeholder Engagement & Cyber Infrastructure Resilience Division (SECIR)

AGENCY: National Protection and Programs Directorate (NPPD), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; new information collection request: 1670—NEW.

SUMMARY: The DHS NPPD Office of Cybersecurity and Communications (CS&C), SECIR, will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this ICR in the **Federal Register** on Tuesday, July 18, 2017 at 82 FR 32859 for a 60-day public comment period. Ten comments from two commenters were received by DHS. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until January 17, 2018. This process is conducted in accordance with 5 CFR part 1320.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. You may send comments, identified by the words ''Department of Homeland Security'' and ''OMB Control Number 1670—NEW (IT Sector Survey)'', by:

- *Email: dhsdeskofficer@omb.eop.gov.* Include ''Department of Homeland Security'' and ''OMB Control Number 1670—NEW (IT Sector Survey)'' in the subject line of the message.

Instructions: Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Reggie McKinney at 703–705–6277 or at *reggie.mckinney@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Section 227 of the Homeland Security Act of 2002 authorizes the National Cybersecurity and Communications Integration Center (NCCIC) within NPPD as a ''Federal civilian interface for the multi-directional and cross-sector sharing of information related to . . . cybersecurity risks.'' 6 U.S.C. 148(c)(1). This authority applies to Federal and non-Federal entities, including the private sector, small and medium businesses, sectors of critical infrastructure, and information sharing organizations. This provision includes the authority to receive, analyze and disseminate information about cybersecurity risks and incidents and to provide guidance, assessments, incident response support, and other technical assistance upon request and codifies NPPD's coordinating role among Federal and non-Federal entities. 6 U.S.C. 148.

As part of its information sharing responsibilities with non-Federal entities, the National Defense Authorization Act For Fiscal Year 2017 (NDAA) amended the Homeland Security Act to authorize the Department to specifically focus on small businesses. See Public Law 114–328 (2016). Specifically, the NDAA authorizes NPPD, through the Secretary, to ''leverage small business development centers to provide assistance to small business concerns by disseminating information on cyber threat indicators, defense measures, cybersecurity risks, incidents, analyses, and warnings to help small business concerns in developing or enhancing cybersecurity infrastructure, awareness of cyber threat indicators, and cyber training programs for employees.'' See 6 U.S.C. 148(l)(1); see also 15 U.S.C. 648(a)(8)(A) (similarly authorizing DHS ''and any other Federal department or agency in coordination with the Department of Homeland Security'' to ''leverage small business concerns by disseminating information relating to cybersecurity risks and other homeland security matters to help small business concerns in developing or enhancing cybersecurity infrastructure, awareness of cyber threat indicators, and cyber training programs for employees'').

Consistent with these authorities, E.O. 13636 directs the Department to increase its cybersecurity information sharing efforts with the private sector and consult on and promote the National Institute of Standards and Technology (NIST) Cybersecurity Framework. To facilitate the Department's promotion of the NIST Cybersecurity Framework, the E.O. directs the Secretary to establish a voluntary program to support the adoption of the Framework in coordination with Sector Specific Agencies, which in turn ''shall coordinate with Sector Coordinating Councils to review the Cybersecurity Framework and, if necessary, develop implementation guidance or supplemental materials to address sector-specific risks and operating environments.'' E.O. 13636, 78 FR 11739 (2013).