

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This draft guidance, when finalized, is intended to update and provide clarity on the Replacement Reagent and Instrument Family Policy for manufacturers of IVD devices and FDA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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices.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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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.

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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]

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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