

information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Anne Hammer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993, 301-796-4642, FAX: 301-847-8510, [anne.hammer@fda.hhs.gov](mailto:anne.hammer@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

One of the three CDRH 2016–2017 Strategic Priorities is to “Partner with Patients”<sup>1</sup> (Ref. 1). This priority reflects and builds on our strong commitment to patients, who are our most important customers. CDRH believes that to successfully achieve this mission, we must consider and engage with patients as partners. With regard to this priority, CDRH also understands that family or care-partners are integral to patient care and management of disease, and we are also committed to engaging them in order to fulfill this mission. FDA will work with both groups to advance the development and evaluation of innovative medical devices and to monitor the performance of marketed devices. In addition, partnerships will be leveraged, by promoting a culture of meaningful patient engagement and interaction between CDRH staff and patients and care-partners.

To achieve this goal, FDA intends to establish a new program, called the Patient and Care-partner Connection (P&CC). This program is designed to provide CDRH staff with a formal process by which they can engage with patients and care-partners to obtain input on key issues. P&CC will broaden CDRH’s exposure to patients’ and care-

partners’ experiences regarding specific disease states and/or medical devices used for the patient’s treatment, diagnosis, or assessment. It will not solicit or provide external policy advice or opinion.

Additionally, P&CC will provide an avenue for designated groups of patients and care-partners to address specific questions pertinent to their treatment, diagnosis, or assessment by partnering with patient organizations in an effort to connect their members with CDRH staff, when the need for input arises. Patient organizations shall be 501(c)(3) organizations that have infrastructure conducive to soliciting patient and caregiver participation, and whose membership possesses relevant experience. Topics will be highly focused and restricted to specified disease states and/or medical devices.

Patients and care-partners will participate in P&CC on a gratuitous basis. Patients and care-partners will also report any conflict of interests they may have that are pertinent to the discussion, although conflicts of interest may not disqualify a patient or care-partner from participating in P&CC.

#### **II. Patient and Care-Partner Connection Program**

The Agency is seeking comments from interested persons on P&CC in general, and on the following questions:

##### *General*

- What are potential barriers to inclusion for patients and care-partners?
- What can FDA do to avoid or remedy any barriers to inclusion?
- What might patients and care-partners see as appropriate and effective engagement with FDA?
- How appropriate is the program title, “Patient and Care-partner Connection”?
- What, if any, other titles should FDA consider?

##### *Inclusion*

- What types of organizations are appropriate for such a partnership?
- What are potential barriers to effective communication between FDA, partner organizations, patients, and care-partners?
- How can FDA engage patients, especially those who are hard to reach or from underserved communities who are typically underrepresented in such initiatives?

##### *Communication*

- What lines of questioning would be considered appropriate?
- What characteristics of such a program might patients and care-

partners view especially positively and/or negatively?

- What methods or qualities of communication might be preferred or convenient for patients and care-partners?

#### **III. Reference**

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, Center for Devices and Radiological Health, “2016–2017 Strategic Priorities,” available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf>.

Dated: October 31, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26784 Filed 11–4–16; 8:45 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA–2013–N–0868]

##### **Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on establishing notification of a consignee and consignee notification of a recipient’s

<sup>1</sup> CDRH’s 2016–2017 Strategic Priorities, in addition to “partner[ing] with patients,” include “Establish a National Evaluation System for Medical Devices” and “Promote a Culture of Quality and Organizational Excellence.”

physician of record regarding a possible increased risk of *Trypanosoma cruzi* (*T. cruzi*) infection.

**DATES:** Submit either electronic or written comments on the collection of information by January 6, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2013-N-0868 for "Guidance for Industry: Use of Serological Tests to Reduce the Risk of the Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### **Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion**

##### **OMB Control Number 0910-0681—Extension**

The guidance document implements the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to *T. cruzi*. The purpose of the donor screening tests is to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of Whole Blood and blood components intended for transfusion. The guidance recommends that establishments that manufacture Whole Blood and blood components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to establishments or to destroy them within 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for *T. cruzi* and positive on a licensed

supplemental test, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the lookback period and, if blood and blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Respondents to this information collection are establishments that manufacture Whole Blood and blood components intended for transfusion. We believe that the information collection provisions in the guidance for establishments to notify consignees and for consignees to notify the recipient's physician of record in the guidance do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and for the consignees to notify the recipient's physician of record.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

Dated: November 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-26792 Filed 11-4-16; 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 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:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Human Tissue Models For Infectious Diseases (U19).

*Date:* December 1-2, 2016.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The William F. Bolger Center, Stained Glass Hall, 9600 Newbridge Drive, Potomac, MD 20854.

*Contact Person:* Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3G41B National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, (240) 669-5047, [bgustafson@niaid.nih.gov](mailto:bgustafson@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Grant (R01).

*Date:* December 16, 2016.

*Time:* 1:00 p.m. to 3:00 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:* Chelsea D. Boyd, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC-9823, Rockville, MD 20852-9834, 240-669-2081, [chelsea.boyd@nih.gov](mailto:chelsea.boyd@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: November 1, 2016.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-26772 Filed 11-4-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel; Research Opportunities in Environmental Health Sciences (R21).

*Date:* November 21, 2016.

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

*Agenda:* To review and evaluate grant applications.

*Place:* NIEHS/National Institutes of Health, Keystone Building, Room 3118, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

*Contact Person:* RoseAnne M. McGee, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, [mccgee1@niehs.nih.gov](mailto:mccgee1@niehs.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 1, 2016.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-26767 Filed 11-4-16; 8:45 am]

**BILLING CODE 4140-01-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