OMB control number 9000–0144. Select the link “Comment Now” that corresponds with “Information Collection 9000–0144, Payment by Electronic Funds Transfer”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 9000–0144, Payment by Electronic Funds Transfer”, on your attached document.
• Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Mandell/IC 9000–0144, Payment by Electronic Funds Transfer.

Instructions: Please submit comments only and cite Information Collection 9000–0144, Payment by Electronic Funds Transfer, in all correspondence related to this collection. Comments received generally will be posted without change to http://www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Zenaida Delgado, Procurement Analyst, via telephone 202–969–7207 or via email to zenaida.delgado@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR requires certain information to be provided by contractors which would enable the Government to make payments under the contract by electronic funds transfer (EFT). The information necessary to make the EFT transaction is specified in clause 52.232–33, Payment by Electronic Funds Transfer—System for Award Management, which the contractor is required to provide prior to award, and clause 52.232–34, Payment by Electronic Funds Transfer—Other than System for Award Management, which requires EFT information to be provided as specified by the agency to enable payment by EFT. This collection of information is mostly imposed on contractors upon award of each contract. Less frequent collection would not facilitate contract payment by EFT as the standard method of payment under Government contracts.

DoD, GSA and NASA analyzed the FY 2016 data from the Federal Procurement Data System (FPDS) to develop the estimated burden hours for this information collection. The burden was adjusted to reflect that the information required by the clause at 52.232–33, Payment by Electronic Funds Transfer—System for Award Management, is already covered by OMB Control Number 9000–0159, System for Award Management Registration (SAM).

B. Annual Reporting Burden

Respondents: 3,761.
Respondents per Respondent: 1.
Annual Responses: 3,761.
Hours per Response: 0.5.
Total Burden Hours: 1,881.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, including whether the information will have practical utility; the accuracy of the estimate of the burden of the information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0144, Payment by Electronic Funds Transfer, in all correspondence.

Dated: December 1, 2017.

Lorin S. Curit,
Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled “Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components; Guidance for Industry.” The guidance document provides recommendations to blood collection establishments regarding the use of serological tests to reduce the risk of transmission of Trypanosoma cruzi (T. cruzi) infection in blood and blood components. The recommendations apply to the collection of blood and blood components, except Source Plasma, for transfusion or for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device. The guidance announced in this notice supersedes the guidance entitled “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” dated December 2010 (2010 Chagas Guidance) and finalizes the draft guidance entitled “Amendment to ‘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’; Draft Guidance for Industry” dated November 2016 (2016 Draft Chagas Guidance). The guidance incorporates recommendations for blood donor testing, deferral, and donor reentry from the 2016 Draft Chagas Guidance.

DATES: The announcement of the guidance is published in the Federal Register on December 6, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, 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–2009–D–0137 for “Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components; Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).
Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3126, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
I. Background
FDA is announcing the availability of a document entitled “Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components; Guidance for Industry.” The guidance document addresses the use of serological tests to reduce the risk of transmission of T. cruzi infection in blood and blood components. The recommendations apply to the collection of blood and blood components, except Source Plasma, for transfusion or for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device. The guidance incorporates recommendations for blood donor testing, deferral, notification, and donor reentry from the 2016 Draft Chagas Guidance. The 2016 Draft Chagas Guidance amended the 2010 Chagas Guidance by (1) expanding the scope of the guidance to include the collection of blood and blood components for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device; (2) removing the recommendation to ask donors about a history of Chagas disease; and (3) providing a recommendation for a reentry algorithm for certain donors deferred on the basis of screening test results for antibodies to T. cruzi or on the basis of answering “yes” to the Chagas screening question. The 2016 Draft Chagas Guidance also provided notice that FDA had licensed a supplemental test for antibodies to T. cruzi and further testing of donations found repeatedly reactive to a screening test for T. cruzi is therefore required under 21 CFR 610.40(e).

In the Federal Register of December 6, 2010 (75 FR 75810), FDA announced the availability of the guidance entitled “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” dated December 2010. In the Federal Register of November 10, 2016 (81 FR 79034), FDA announced the availability of the draft guidance entitled “Amendment to ‘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’; Draft Guidance for Industry” dated November 2016. FDA received two comments on the 2016 Draft Chagas Guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice supersedes the 2010 Chagas Guidance and finalizes the 2016 Draft Chagas Guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components.” 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.
II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The guidance refers to the following collections of information: (1) Establishments notify consignees of all previously collected in-date blood and blood components from a donor that tests repeatedly reactive by a licensed test for T. cruzi antibody to quarantine and return the blood and blood components to the establishments or to destroy them; (2) establishments notify consignees of all previously distributed blood and blood components collected from such a donor during the lookback period; and (3) if such blood components were transfused, consignees notify the recipient’s physician of record of a possible increased risk of T. cruzi infection. These collections of information have been approved under OMB control number 0910–0681.

This guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 606, 610, and 630 have been approved under OMB control numbers 0910–0116 and 0910–0795.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: November 30, 2017.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 materials, 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 Advisory Neurological Disorders and Stroke Council.

Date: February 1, 2018.

Open: February 1, 2018, 8:00 a.m. to 3:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: February 1, 2018, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Robert Finkelstein, Ph.D., Director, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, Bethesda, MD 20892, (301) 496–9248.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into Federal buildings. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

Information is also available on the Institute’s/Center’s home page: http://www.ninds.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: November 30, 2017.

Sylvia L. Neal,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Neurological Disorders and Stroke, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: January 28–30, 2018.

Time: 6:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

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

Contact Person: Alan P. Koretsky, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, NIH, 35 Convent Drive, Room 6A 908, Bethesda, MD 20892, (301) 435–2232, koretsky@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: November 30, 2017.

Sylvia L. Neal,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P