Blood Safety.” The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for blood components intended for transfusion. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

DATES: The public workshop will be held on November 29, 2018, from 8 a.m. to 5 p.m., and on November 30, 2018, from 9 a.m. to 1 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–8010, email: CBERPublicEvents@fda.hhs.gov (subject line: Pathogen Reduction Technology and Blood Safety).

SUPPLEMENTARY INFORMATION:

I. Background

Pathogen reduction technology has the potential to improve blood safety by reducing or eliminating infectious organisms, including bacteria, viruses, and parasites, from blood components intended for transfusion. FDA granted approvals for use of a pathogen reduction technology platform in manufacturing plasma and apheresis platelets for transfusion. Ideally, pathogen reduction technology should also be available for whole blood and red blood cells. Implementation of safe and effective pathogen reduction technology may also permit alternative donor screening or donation testing strategies in the future. The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for all blood components intended for transfusion.

II. Topics for Discussion at the Public Workshop

The first day of the workshop will include presentations and panel discussions on the following topics: (1) Transfusion-transmitted infectious agents and their impact on blood safety; (2) status of pathogen reduction technology for blood components intended for transfusion, including challenges to implementation in the United States; and (3) the development of pathogen reduction technology for whole blood and red blood cells.

The second day of the workshop will include presentations and panel discussions on the following topics: (1) Emerging pathogen reduction technologies and alternative approaches to controlling risk; (2) potential funding opportunities for research; and (3) a summary of all workshop sessions, panel discussions, and future directions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by November 8, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided, beginning at 7 a.m.

If you need special accommodations, due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than November 19, 2018 (see FOR FURTHER INFORMATION CONTACT). Request for sign language interpretation or Computer Aided Realtime Translation (CART)/captioning should be made 2 weeks in advance of the event, no later than November 15, 2018. A request for either interpreting or captioning should be sent directly to the FDA Interpreting Services Staff email account: interpreting.services@oc.fda.gov.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Individuals who wish to view the webcast should register for the workshop at https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605. A link to the live webcast will be provided upon registration.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document as of the date this document publishes in the Federal Register, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/default.htm.


Leslie Kux,
Associate Commissioner for Policy.
updates on work from the previous meetings and federal workgroup updates.

DATES: The meeting will be held on October 19, 2018 from 9 a.m. to 5 p.m. EDT.

ADDRESS: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to napa@hhs.gov. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, rohini.khillan@hhs.gov. Note: Seating may be limited. Those wishing to attend the meeting must send an email to napa@hhs.gov and put “October 19 Meeting Attendance” in the Subject line by Wednesday, October 10, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: During the October meeting, the Long-Term Services and Supports Subcommittee will be taking charge of the theme. The topics covered will include: (1) The experience of people with dementia who have special needs due to issues like diversity, geography, and concurrent disorders; (2) How clinical care can be better integrated with community-based supports and services; and (3) Evidence-based behavioral approaches that mitigate the impact of behavioral symptoms of dementia. The meeting will also include updates on work from the previous meetings and federal workgroup updates.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at www.hhs.gov/live.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer’s Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.


Brenda Destro,
Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: 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.


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

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, 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.

Date: October 9–10, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Drive, Chicago, IL 60601.

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, rojasr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Behavioral Genetics and Epidemiology.

Date: October 10, 2018.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Karen Nieves Lugo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, karen.nieveslug@nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: October 11–12, 2018.

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

Agenda: To review and evaluate grant applications.