DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES:

- September 13, 2022, 9 a.m.–4 p.m. Central Time (CT);
- September 14, 2022, 9 a.m.–5 p.m. CT; and
- September 15, 2022, 9 a.m.–12 p.m. CT.

ADDRESSES: This meeting will be conducted in-person at Mystic Lake Center, 2400 Mystic Lake Blvd. NW, Prior Lake, MN 55372. The meeting will also be held via webinar. *The webinar link and log-in information will be available at ACIMM's website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.* Refer to the ACIMM website for any updated information concerning the meeting, including the potential for the meeting to be held virtually only via webinar. If the meeting is changed to virtual only, an update will be posted on the website listed above on or about August 30, 2022.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees.

The ACIMM advises the Secretary of HHS on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve these outcomes, as well as influence similar efforts in the private and voluntary sectors. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee also advises the Secretary of HHS on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the September 13–15, 2022, meeting is being finalized and may include the following topics: infant and maternal mortality among American Indian/Alaska Native (AI/AN) women and infants; indigenous health; and federal program updates. In addition to these topics, it is expected that there will be a discussion of recommendations by the ACIMM to the Secretary of HHS on improving birth outcomes among AI/AN mothers and infants, and then a vote on whether to send the recommendations forward to the Secretary of HHS. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to the ACIMM should be sent to Vanessa Lee, using the email address above, at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing *SACIM@hrsa.gov.* Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or some reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–17487 Filed 8–12–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Department of Health and Human Services

Office of the Secretary; Emergency Use Authorization; Monkeypox Virus Vaccine

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On August 9, 2022, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.

On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of vaccines for use against monkeypox virus pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are valid August 9, 2022.

FOR FURTHER INFORMATION CONTACT: Dawn O'Connell, Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing: (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk

of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the Commissioner of Food and Drugs may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The ASPR requested that the Secretary issue the determination and declaration to allow the Department to take measures based on information currently available about monkeypox virus. The determination of a public health emergency or a significant potential for a public health emergency, and the declaration that circumstances exist justifying emergency use of vaccines by the Secretary of HHS, as described below, enable the Commissioner of Food and Drugs to issue an EUA for vaccines for emergency use under section 564 of the FD&C Act.

[1] 42 U.S.C. 247d–6b.

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113–5, the Secretary may make a determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On August 9, 2022, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad that involves monkeypox virus.

III. Declaration of the Secretary of Health and Human Services

Also on August 9, 2022, on the basis of my determination that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad and that involves monkeypox virus, I declared that circumstances exist justifying the authorization of emergency use of vaccines pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the Commissioner of Food and Drugs pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: August 10, 2022.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2022–17503 Filed 8–12–22; 8:45 am]

BILLING CODE 4150–37–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 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 Neurological Disorders and Stroke Special Emphasis Panel; Emergency Care Clinical Trials Panel 1.

Date: August 18, 2022.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate cooperative agreement applications.

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

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892, 301–435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: August 9, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17453 Filed 8–12–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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: Center for Inherited Disease Research Access Committee.

Date: September 9, 2022.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20892 (Virtual Meeting).