

evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 11, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 12, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov) or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-06747 Filed 3-31-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Emergency Use Authorization Declaration

**AGENCY:** Department of Health and Human Services.

**ACTION:** [Notice of Emergency Use Authorization Declaration.](#)

**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 February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health

emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

**DATES:** The determination was effective February 4, 2020, and [this declaration is effective March 27, 2020.](#)

**FOR FURTHER INFORMATION CONTACT:**

Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, 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 the 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 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

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 FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for drugs and biological products to allow the Department to take response measures based on information currently available about the virus that causes COVID-19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of drugs and biological products by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for drugs and biological products for emergency use under section 564 of the FD&C Act.

**II. Determination by the Secretary of Health and Human Services**

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

**III. Declaration of the Secretary of Health and Human Services**

On March 27, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, I declared that circumstances exist justifying the [authorization of emergency use of drugs](#)

and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUs issued by the FDA Commissioner 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: March 27, 2020.

**Alex M. Azar II,**

Secretary.

[FR Doc. 2020-06905 Filed 3-30-20; 2:00 pm]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Regents, May 12-13, 2020, 9:00 a.m. to 4:00 p.m. at the National Institutes of Health, Building 38, Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892 which was published in the **Federal Register** on February 4, 2020, 85 FR 23, Page 6210.

This notice is being amended to change the meeting location from the National Institutes of Health, Building 38, Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892 to a virtual meeting. The URL link to this meeting is: <https://videocast.nih.gov>. Any member of the public may submit written comments no later than 15 days after the meeting.

Dated: March 27, 2020.

**Ronald J. Livingston, Jr.,**

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-06768 Filed 3-31-20; 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 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 Scientific Review Special Emphasis Panel; Member Conflict: Health Informatics and Health Care Delivery.

*Date:* April 10, 2020.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ping Wu, Ph.D., Scientific Review Officer, HDM IRC, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301-451-8428, [wup4@csr.nih.gov](mailto:wup4@csr.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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 26, 2020.

**Ronald J. Livingston, Jr.,**

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-06766 Filed 3-31-20; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 Investigator-Initiated Clinical Trial Planning Grant (R34).

*Date:* April 23, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Kelly L. Hudspeth, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240-669-5067, [kelly.hudspeth@nih.gov](mailto:kelly.hudspeth@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: March 26, 2020.

**Tyeshia M. Roberson,**

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-06765 Filed 3-31-20; 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 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 Scientific Review Special Emphasis Panel; PAR 19-059: Global Noncommunicable Diseases and Injury Across the Lifespan (R21).

*Date:* April 10, 2020.

*Time:* 10:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Weijia Ni, Ph.D., Chief Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100,