receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) no later than April 3, 2020.

*Requests for Oral Presentations:* During online registration you may indicate if you wish to present during a public comment session for a specific breakout session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 10, 2020. All requests to make oral presentations must be received by the close of registration on April 3, 2020, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than April 24, 2020, midnight Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Persons attending FDA's workshops are advised that FDA is not responsible for providing access to electrical outlets.

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast. Please register online by April 3, 2020, midnight Eastern Time to attend the workshop remotely. Please note that remote attendees will not be able to speak or make presentations during the public comment session or during any other session of the workshop. To join the main sessions of the workshop via the webcast, please go to *https://collaboration.fda.gov/gdrsipw2020/.* Webcast information for the four breakout sessions will be provided separately via email upon successful 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* or at *https://www.fda.gov/gdufaregscience.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufaregscience.*

Dated: March 4, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–04866 Filed 3–9–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Emergency Use Declaration

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**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 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 personal respiratory protective devices during the COVID–19 outbreak, 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 2, 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,[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

[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 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.

exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of such an authorization under section 564 of the FD&C Act are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the FDA, HHS, issue an EUA for personal respiratory protective devices to allow the Department to take preparedness 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 personal respiratory protective devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for respiratory protective devices 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 2, 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 personal respiratory protective devices during the COVID–19 outbreak, 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 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.

**Alex M. Azar II,**

*Secretary.*

[FR Doc. 2020–04823 Filed 3–9–20; 8:45 am]

**BILLING CODE 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; Investigator Initiated Extended Clinical Trial (R01 Clinical Trial Required).

*Date:* March 24, 2020.

*Time:* 1:00 p.m. to 6:00 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 3G53A, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Julio C. Aliberti, Ph.D., Scientific Review Officer, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53A, Rockville, MD 20892–9823, 301–761–7322, *julio.aliberti@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 4, 2020.

**Tyeshia M. Roberson,**

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

[FR Doc. 2020–04780 Filed 3–9–20; 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; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

*Date:* April 6–8, 2020.

*Time:* 8:00 a.m. to 1:00 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 3F21B, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Bethesda, MD 20892–9834, (240) 669–5026, *haririmf@niaid.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 4, 2020.

**Tyeshia M. Roberson,**

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

[FR Doc. 2020–04782 Filed 3–9–20; 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 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