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 the U.S. Department of Health and Human Services (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 of attack with a CBRN agent or agents; or (4) a determination by the Secretary of HHS 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 nerve agents or certain insecticides (organophosphorus and/or carbamate).

On the basis of this determination, the Secretary also declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent and certain insecticide (organophosphorus and/or carbamate) poisoning pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

III. Declaration of the Secretary of Health and Human Services

On April 11, 2017, on the basis of my determination of a significant potential for 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 nerve agents or certain insecticides (organophosphorus and/or carbamate), I determined that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

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 Centers for Disease Control and Prevention (CDC) requested that the FDA issue an EUA for use of an injectable treatment for nerve agent and certain insecticide (organophosphorus and/or carbamate) poisoning to support preparedness and response to potential public health threats posed by these agents and compounds. At this time, FDA-approved injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning are not available to replenish the Department’s Strategic National Stockpile inventory when the products in the current inventory expire. Pending the availability of such products, an EUA will facilitate ensuring that the products are available in the event of a public health emergency involving nerve agent or certain insecticides (organophosphorus and/or carbamate). The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning by the Secretary of HHS, as described below, enables the FDA Commissioner to issue an EUA for certain injectable treatments for emergency use under section 564 of the FD&C Act.

On April 11, 2017, pursuant to section 564 of the FD&C Act, I determined that there is a significant potential for 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 nerve agents or certain insecticides (organophosphorus and/or carbamate).
carbamate), I declared that circumstances exist justifying the authorization of emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any 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.


Thomas E. Price, Secretary.

[FR Doc. 2017–07685 Filed 4–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; TOPMed Informatics Research Center (IRC).


(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)


Michelle Trout, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–07618 Filed 4–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13/U13).

Date: May 9–11, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3C11A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5045, sundstromj@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01/R01).

Date: May 10, 2017.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Yong Gao, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G13B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–7616, (240) 669–5048, yong.gao@nih.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases