reasonable accommodations, should notify the Advisory Council at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/ash/carb/.*

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing *CARB@hhs.gov.* Public comments should be sent in by midnight April 25, 2017, and should be limited to no more than one page. All public comments received prior to April 25, 2017, will be provided to Advisory Council members; comments are limited to two minutes per speaker.

Dated: April 12, 2017.

Jewel Mullen,

Acting Director, National Vaccine Program Office.

[FR Doc. 2017–07708 Filed 4–14–17; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of Injectable Treatments for Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning

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 April 11, 2017, the Secretary 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).

On the basis of this determination, he also 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.

DATES: The determination and declaration are effective April 11, 2017.

FOR FURTHER INFORMATION CONTACT: George Korch, Ph.D., Acting 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 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 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 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 [3] 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.

II. Determination by the Secretary of Health and Human Services

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).[1]

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

[1] 42 U.S.C. 247d–6b(c).

[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.

[3] 42 U.S.C. 247d–6b(a).

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.

Dated: April 11, 2017.

Thomas E. Price,

Secretary.

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

BILLING CODE P

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).

Date: May 9, 2017.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–435–0725, *johnsonwj@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; TOPMed Data Coordinating Center (DCC).

Date: May 9, 2017.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–435–0725, *johnsonwj@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 11, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–07618 Filed 4–14–17; 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 (5 U.S.C. App.), 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–15–276: Turkey-US Collaborative Program for Affordable Medical Technologies (R01).

Date: May 5, 2017.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

(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: April 11, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–07617 Filed 4–14–17; 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 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 Official, Scientific Review Program, Division of Extramural Activities, Room 3G11A, 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*.