

serves as Director of the National Vaccine Program.

During the June 2017 NVAC meeting, sessions will include an update on the Secretary of the Department of Health and Human Services' report on vaccine innovation to Congress in response to the 21st Century Cures Act; presentations on immunization information systems and inter-jurisdictional data exchange; and an update on vaccine confidence-related projects. Please note that agenda items will be related to the charge of the Committee and are subject to change as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC Web site: <http://www.hhs.gov/nvpo/nvac/index.html>.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend in person and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone 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/nvpo/nvac/meetings/index.html>.

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (nvpo@hhs.gov) at least five business days prior to the meeting.

Dated: March 23, 2017.

Jewel Mullen,

Acting Director, National Vaccine Program Office.

[FR Doc. 2017-07707 Filed 4-14-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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

Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to CARB@hhs.gov. Registration information is available on the Web site <http://www.hhs.gov/ash/carb/> and must be completed by April 25, 2017; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

DATES: The meeting is scheduled to be held on May 3, 2017, from 9:00 a.m. to 5:00 p.m. ET, and May 4, 2017, from 9:00 a.m. to 3:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the Web site for the Advisory Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than April 25, 2017; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690-5566; email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated

September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The first day of the public meeting, May 3, 2017, will be dedicated to the topic of Infection Prevention and Control for Animal Health. The three working groups on Incentives for Diagnostics, Therapeutics/Anti-Infectives, and Vaccines, will report their preliminary findings to the full Advisory Council for deliberation on the second day of the public meeting, May 4, 2017; no vote will be held. The meeting agenda will be posted on the Advisory Council Web site at <http://www.hhs.gov/ash/carb/> when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

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]

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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) Act¹ 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

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.

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 Stockpile³ 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

³ 42 U.S.C. 247d-6b(a).