posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., 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, 1101 Wootton Parkway, Rockville, MD 20852. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), 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 PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The March 23–24, 2023 will be a two-day meeting that will focus on the report out from the Pandemic Preparedness Working Group as they present their findings in response to the 2022 task from the HHS Secretary in a report with recommendations to the full PACCARB for deliberation and vote. Upon completion of the voting process, the PACCARB will honor its retiring members. The meeting will also include updates from the international sector on progress in the ongoing fight against antimicrobial resistance and an exploration of future topics for the PACCARB to consider in the following year. The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items are tentative and subject to change. Instructions regarding attending the meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments in-person during the March meeting by pre-registering online at *http://www.hhs.gov/paccarb.* Pre-registration is required for participation in this session with limited spots available. Written public comments can also be emailed to *CARB@hhs.gov* by midnight March 17, 2023 and should be limited to no more than one page. All public comments received prior to March 17, 2023, will be provided to the PACCARB members. Additionally, companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the PACCARB live during an Innovation Spotlight. Pre-registration is required for participation, with limited spots available. All information regarding this session can also be found online at *http://www.hhs.gov/paccarb.*

Dated: January 12, 2023.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2023–02921 Filed 2–9–23; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Termination of Declaration Authorizing Emergency Use of New In Vitro Diagnostics for Detection of Enterovirus D68

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 6, 2015, pursuant to section 564 of the FD&C Act, Sylvia M. Burwell, former Secretary of HHS, determined that there was a significant potential for a public health emergency that had a significant potential to affect national security or the health and security of United States citizens living abroad and that involved enterovirus D68 (EV–D68). Also on February 6, 2015, based on that determination, former Secretary Burwell declared that circumstances existed justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. As of September 2022, the Centers for Disease Control and Prevention's (CDC's) EV–D68 2014 rRT–PCR for which an EUA was issued is no longer produced and all test kits were destroyed. CDC's EV–D68 2014 rRT–PCR was never distributed. On February 6, 2023, pursuant to section 564 of the FD&C Act, the Secretary of HHS determined that there is no longer 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 EV–D68. The Secretary of HHS also determined that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 no longer exist. Based on these determinations, the Secretary of HHS terminated the declaration, effective February 20, 2023, that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 exist.

DATES: Termination of the declaration is effective February 20, 2023.

FOR FURTHER INFORMATION CONTACT: Dawn O'Connell, Assistant Secretary for Preparedness and Response,

Administration for Strategic Preparedness and Response, 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 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 biological, chemical, 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.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point FDA may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

A declaration justifying an authorization under section 564 of the FD&C Act terminates upon the earlier of: a determination by the Secretary of HHS, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances justifying emergency authorization have ceased to exist; or a change in the approval status of the product under emergency authorization such that the product is no longer unapproved, unlicensed, or uncleared, or is no longer intended for an unapproved use.

The Secretary must provide advance notice of any termination of a declaration under section 564 of the FD&C Act. The period of advance notice must be a period reasonably determined to provide: in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with section 564(f)(2) of the FD&C Act) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and, in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under section 564(e)(2)(B)(ii) of the FD&C Act, as the case may be, that was provided with respect to the emergency use involved. If an EUA for an unapproved product issued by FDA ceases to be effective due to the termination of the Secretary of HHS's declaration justifying emergency use, the Secretary of HHS shall consult with the manufacturer of such product with respect to the appropriate disposition of the product. As of September 2022, the CDC's EV–D68 2014 rRT–PCR, which is the only EUA issued under the Secretary's declaration, is no longer produced and all test kits were destroyed. CDC's EV–D68 2014 rRT–PCR was never distributed. Therefore, a 14-day period of advance notice has been determined to be sufficient, as disposition of the only associated product is already complete.

[1] 42 U.S.C. 247d–6b, which states: ''[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.''

II. Determination of a Significant Potential for a Public Health Emergency and Declaration That Emergency Use Is Justified by the Secretary of Health and Human Services

On February 6, 2015, pursuant to section 564 of the FD&C Act, Sylvia M. Burwell, former Secretary of HHS, determined that there was a significant potential for a public health emergency that had a significant potential to affect national security or the health and security of United States citizens living abroad and that involved EV–D68. Also on February 6, 2015, based on that determination, former Secretary Burwell declared that circumstances existed justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

III. Determination of the Secretary of Health and Human Services Terminating Declaration That Emergency Use Is Justified

On February 6, 2023, pursuant to section 564 of the FD&C Act, the Secretary of HHS determined that there is no longer 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 EV–D68. Also, on February 6, 2023, the Secretary of HHS determined that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 no longer exist. Based on these determinations, the Secretary of HHS terminated, effective February 20, 2023, the declaration that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 exist.

This **Federal Register** notice serves as advance notice that this declaration will be terminated, effective February 20, 2023, as required under section 564 of the FD&C Act. Notice of termination of an EUA issued by FDA pursuant to this declaration will be provided by FDA in the **Federal Register**, as required under section 564 of the FD&C Act.

Dated: February 7, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–02872 Filed 2–9–23; 8:45 am]

BILLING CODE 4150–37–P