September 18, 2014, authority was given to the Secretary of Health and Human Services to establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council), in consultation with the Secretaries of Defense (DoD) and Agriculture (USDA). 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 (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan). 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 March public meeting will be dedicated to presentations by the five currently active working groups of the Advisory Council, which are: Antibiotic Stewardship; One Health Surveillance; Diagnostic Innovations; Treatment, Prevention and Control Research and Development; and International Collaboration on Combating Antibiotic-Resistant Bacteria (CARB). The Advisory Council will deliberate and vote on the working groups' findings and recommendations. In addition, the Advisory Council will be presented with a new task(s) from the Secretary of HHS, in consultation with USDA and DoD. The meeting agenda will be posted on the Advisory Council Web site at *http://www.hhs.gov/ash/carb* when it has been finalized.

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 March 21, 2016, and should be limited to no more than one page. All public comments received prior to March 21, 2016, will be provided to Advisory Council members and read during the public comment period designated on the agenda; comments are limited to two minutes per speaker.

Dated: February 25, 2016.

Bruce Gellin,

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

[FR Doc. 2016–04473 Filed 3–1–16; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection

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, 21 U.S.C. 360bbb–3. On February 26, 2016, 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 Zika virus.

On the basis of this determination, she also declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection 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 February 26, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., MSPH, 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 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

[1] 42 U.S.C. 247d–6b.

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 *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection to allow the Department to take preparedness measures based on information currently available about the active transmission of Zika virus, as of February 24, 2016, in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, 31 countries in the Americas, Pacific Islands, and Africa. On February 1, 2016, the World Health Organization declared a Public Health Emergency of International Concern because of clusters of microcephaly and other neurological disorders in some areas affected by Zika virus. On January 22, 2016, CDC activated its Incident Management System and, working through the Emergency Operations Center, centralized its response to the outbreaks of Zika occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika virus. On February 8, 2016, CDC elevated its response efforts to a Level 1 activation, the highest response level. The Secretary's Operations Center, which is operated by the Office of the Assistant Secretary of Preparedness and Response, is also activated. The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for certain diagnostic tests for emergency use under section 564 of the FD&C Act.

[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.

II. Determination by the Secretary of Health and Human Services

On February 26, 2016, pursuant to section 564 of the FD&C Act, I determined that a 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 Zika virus.

III. Declaration of the Secretary of Health and Human Services

Also on February 26, 2016, 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 Zika virus, I declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection 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: February 26, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–04624 Filed 3–1–16; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–DHS–2016–0019]

Agency Information Collection Activities: Submission for Review; Information Collection Request for the Department of Homeland Security Science & Technology Technology Acceptance and Evaluation Survey

AGENCY: Science and Technology Directorate, DHS.

ACTION: 60-Day notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS) invites the general public to comment on the data collection form for the DHS Science & Technology Directorate (S&T) Technology Acceptance and Evaluation (TAE) Survey. The TAE web based tool proposes to collect information from 1,200 members of an online Internet panel. All information collected will be on a voluntary basis. DHS will not receive any personally identifying information. As part of its core mission, DHS is tasked with preventing terrorism and enhancing security, securing and managing our borders, and ensuring resilience to disasters. In order to assist in those key mission spaces, the S&T managed work to create a Rapid DNA Technology that allows field testing of DNA that is inexpensive and quick while performing with high accuracy in a non-laboratory setting. To ensure the effective implementation and diffusion of this new technology, DHS S&T seeks to better understand public perceptions of Rapid DNA, its use cases, and its collection through the TAE Survey. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Comments are encouraged and will be accepted until May 2, 2016.

ADDRESSES: Interested persons are invited to submit comments, identified by docket number DHS–2016–0019, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Email: Kathleen.Deloughery@hq.dhs.gov.* Please include docket number DHS–DHS–2016–0019 in the subject line of the message.
- *Fax:* (202) 254–6911. (Not a toll-free number).
- *Mail:* Science and Technology Directorate, ATTN: Kathleen Deloughery 6–055, 245 Murray Lane, Mail Stop 0210, Washington, DC 20528–0210.

FOR FURTHER INFORMATION CONTACT: DHS FRCoP Contact Kathleen Deloughery (202) 254–6189 (Not a toll free number).

SUPPLEMENTARY INFORMATION: The Department is committed to improving its information collection and urges all interested parties to suggest how these materials can further reduce burden while seeking necessary information under the Act.

DHS is particularly interested in comments that:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and