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

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

[1] 42 U.S.C. § 247d-6b

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 *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

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 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.

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.

II. Determination by the Secretary of Health and Human Services

On February 26, 2016, pursuant to section 564of 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

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