4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2044]

Termination of Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Enterovirus D68

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the May 12, 2015, Emergency Use Authorization (EUA) (authorization) issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the Centers for Disease Control and Prevention's (CDC) Enterovirus D68 (EV-D68) 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR) (CDC EV-D68 EUA). Issuance of the CDC EV-D68 EUA was supported by former Secretary of Health and Human Services (HHS) Sylvia M. Burwell's February 6, 2015, declaration that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV-D68, pursuant to the FD&C Act. On February 6, 2023, the Secretary of HHS terminated the February 6, 2015, declaration, effective February 20, 2023, an action that automatically terminated any EUAs issued by the FDA pursuant to the declaration, in this case, the CDC EV-D68 EUA.

DATES: The CDC EV-D68 EUA is terminated as of February 20, 2023.

ADDRESSES: Submit written requests for single copies of the EUA termination to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the EUA termination may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the EUA termination.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. EUA Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), 21st Century Cures Act of 2016 (Pub. L. 114-255), and Pub. L. 115-92 (2017), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (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 agent or agents; (2) 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 U.S. military forces, including personnel operating under the authority of title 10 or title 50, United States Code, 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 U.S. military forces; (3) 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 U.S. citizens living

abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of CDC (to the extent feasible and appropriate given the applicable circumstances), FDA[1] concludes that the statutory criteria for issuance of an EUA are met.

Under section 564(b)(2) of the FD&C Act, an EUA declaration shall be terminated upon the earlier of: (1) a determination by the Secretary of HHS that the circumstances described in the EUA declaration have ceased to exist or (2) a change in the approval status of the product. Under section 564(b)(3) (4) of the FD&C Act, HHS shall provide advance notice that an EUA declaration will be terminated and shall publish in the *Federal Register* the advance notice of termination. Termination of an EUA declaration will automatically terminate any EUAs that FDA issued under the declaration. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each EUA, and each termination or revocation of an EUA, and an explanation of the reasons for the action.

II. EUA Declaration and EUA for EV-D68 2014 rRT-PCR

On February 6, 2015, Sylvia M. Burwell, former Secretary of HHS, 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 U.S. citizens living abroad and that involves EV-

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

D68. On the basis of such determination, on February 6, 2015, the former Secretary of HHS also declared that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV-D68, subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a) (80 FR 10685). On May 12, 2015, and on the basis of the February 6, 2015, HHS declaration, FDA issued the CDC EV-D68 EUA. Notice of the issuance of the EUA was published in the *Federal Register* on July 1, 2015 (80 FR 37625).

On September 12, 2022, CDC requested the Secretary of HHS to terminate the February 6, 2015, determination, and as a result, FDA to revoke the CDC EV-D68 EUA. The 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. 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 February 6, 2015, declaration that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV-D68. Advance notice of the termination of the February 6, 2015, declaration was published in the *Federal Register* on February 10, 2023, as required under section 564 of the FD&C Act (88 FR 8874). Termination of the February 6, 2015, declaration automatically terminated the CDC EV-D68 EUA, which was the only EUA issued under the declaration.

III. Electronic Access

An electronic version of this document is available on the internet at https://www.regulations.gov.

IV. Notice of EUA Termination

Based on the Secretary of HHS's February 6, 2023, termination of the February 6, 2015, declaration that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV-D68, FDA is issuing, under section 564(h)(1) of the FD&C Act, this notice of termination of the May 12, 2015, CDC EV-D68 EUA. Section 564(h)(1) of the FD&C Act requires FDA to provide notice of each termination of an authorization under section 564 of the FD&C Act, and an explanation of the reasons therefor.

Dated: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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