



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of in Vitro Diagnostics for Detection of the Avian Influenza A (H7N9) Virus

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(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. § 360bbb-3(b)(4). On April 19, 2013, 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 the avian influenza A (H7N9) virus.

On the basis of this determination, she also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus pursuant to section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), subject to the terms of any authorization issued under that section. The Secretary also specified

that this declaration is a declaration of an emergency with respect to in vitro diagnostics as defined under the Public Readiness and Emergency Preparedness (PREP) Act Declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices signed by then Secretary Michael Leavitt on December 17, 2008.¹

DATES: The determination and declaration are effective April 19, 2013.

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): 1) authorizing 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 an emergency justifying the authorization based on one of four determinations: 1) a determination of a domestic emergency, or a

¹ 73 Fed. Reg. 78362 (Dec. 22, 2008)

significant potential for a domestic emergency, by the Secretary of Homeland Security; 2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act² sufficient to affect national security or the health and security of United States citizens living abroad; 3) a determination of a military emergency, or a significant potential for a military emergency, by the Secretary of Defense; 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 biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents (see 21 U.S.C. § 360bbb-3(b)(1)).³

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), HHS, requested that the FDA, HHS, issue an EUA for in vitro diagnostics for detection of the avian influenza A (H7N9) virus to allow the Department to take preparedness measures based on information currently available about the avian influenza A (H7N9) virus detected in China. The determination of a significant potential for a public health emergency, and the declaration that circumstances exist justifying

² 42 U.S.C. § 247d-6b

³ 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.

emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for certain in vitro diagnostics for emergency use under section 564(a) of the FD&C Act, 21 U.S.C. § 360bbb-3(a).

II. Determination by the Secretary of Health and Human Services

On April 19, 2013, pursuant to section 564(b)(1)(C) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1)(C), 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 the avian influenza A (H7N9) virus.

III. Declaration of the Secretary of Health and Human Services

Also on April 19, 2013, 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 the avian influenza A (H7N9) virus, I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus pursuant to section 564 of the FD&C Act, 21 U.S.C. § 360bbb-3, subject to the terms of any authorization issued under that section.

I also specified that this declaration is a declaration of an emergency with respect to in vitro diagnostics as defined under the PREP Act Declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices signed by then Secretary Michael Leavitt on December 17, 2008.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under 21 U.S.C. § 360bbb-3(h).

April 19, 2013

Dated

Kathleen Sebelius

Secretary

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