

## DECLARATION OF EMERGENCY PURSUANT TO SECTION 564 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. 360bbb-3(b)

On the basis of the April 26, 2009, determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. § 247d, that a public health emergency exists nationwide involving Swine Influenza A (now called 2009 H1N1 flu) that affects or has significant potential to affect national security, and my renewal of that determination on July 24, 2009, October 1, 2009, December 28, 2009, and March 26, 2010, because the 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure we are prepared, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b), I, Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, hereby renew the April 27 2009, declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a). This declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 Fed. Reg. 78362 (December 22, 2008).

MAR 2 6 2010

Date

Kathleen Sebelius Secretary



## DECLARATION OF EMERGENCY PURSUANT TO SECTION 564 OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C. 360bbb-3(b)

On the basis of the April 26, 2009, determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. § 247d, that a public health emergency exists nationwide involving Swine Influenza A (now called 2009 H1N1 flu) that affects or has significant potential to affect national security, and my renewal of that determination on July 24, 2009, October 1, 2009, December 28, 2009, and March 26, 2010, because the 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure we are prepared, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b), I, Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, hereby renew the April 26 2009, declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of certain in vitro diagnostics for detection of Swine Influenza A (now called 2009 H1N1 flu) accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a). This declaration is a declaration of emergency, as defined in the December 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 Fed. Reg. 78362 (December 22, 2008).

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On the basis of the April 26, 2009, determination by then Acting Secretary Charles E. Johnson, pursuant to section 319 of the Public Health Service Act, 42 U.S.C. § 247d, that a public health emergency exists nationwide involving Swine Influenza A (now called 2009 H1N1 flu) that affects or has significant potential to affect national security, and my renewal of that determination on July 24, 2009, October 1, 2009, December 28, 2009, and March 26, 2010 because the 2009 H1N1 flu outbreak remains a public health threat and the Department should use all available tools to ensure we are prepared, and pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b), I, Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, hereby renew the April 26, 2009, declaration by then Acting Secretary Charles E. Johnson of an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals, oseltamivir phosphate and zanamivir, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a). This declaration is a declaration of emergency, as defined in the October 10, 2008, Declaration under the Public Readiness and Emergency Preparedness Act for Influenza Antivirals Oseltamivir Phosphate and Zanamivir, 73 Fed. Reg. 61861 (October 17, 2008), as amended at 74 Fed. Reg. 2913 (April 26, 2009).

MAR 2 6 2010

Date

Kathleen Sebelius

Secretary



## RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

Because the 2009 H1N1 flu outbreak remains a worldwide public health threat and the Department should use all available tools to ensure that we are prepared, on this date and after consultation with public health officials as necessary, I, Kathleen Sebelius, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, 42 U.S.C § 247d, do hereby renew the April 26, 2009 determination by then Acting Secretary Charles E. Johnson, which I previously renewed on July 24, 2009, October 1, 2009, and December 28, 2009 that a public health emergency exists nationwide involving Swine Influenza A (now called 2009 H1N1 flu) that affects or has significant potential to affect national security.

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Kathleen Sebelius Secretary