

HHS Secretary's Amendment to the Declaration for the Use of the Public Readiness and Emergency Preparedness Act for the Influenza Antivirals Oseltamivir Phosphate (Tamiflu®) and Zanamivir (Relenza®) Dated October 10, 2008

Whereas the October 10, 2008 declaration for Oseltamivir Phosphate (Tamiflu®) and Zanamivir (Relenza®) ("Original Declaration") applies to administration of the aforementioned covered countermeasures to address the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian influenza A viruses or other highly pathogenic influenza viruses causing a pandemic following exposure to the viruses;

Whereas the current detection of H1N1 swine flu in Mexico and the United States may have the potential to evolve into an influenza strain capable of causing a pandemic of human influenza;

Whereas the aforementioned covered countermeasures may be effective to protect persons from either the threat of H1N1 swine influenza, or to treat persons with H1N1 swine influenza;

Whereas the findings made by the Secretary in the Original Declaration continue to apply generally, and apply with equal force as to swine influenza;

Whereas in accordance with section 319F-3(b)(6) of the Act (42 U.S.C. 247d-6d(b), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or approval, and use of additional covered countermeasures with respect to the category of disease in section II of the Original Declaration, as amended, and have found it desirable to encourage such activities for these additional covered countermeasures, and;

Whereas to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or approval, and use of medical countermeasures with respect to the category of disease described in section II of the Original Declaration, as amended, it is advisable, in accordance with section 319F-3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F-3(i)(2) of the Act, and to include as such covered

persons such other qualified persons as I have identified in section VI of the Original Declaration, as amended;

Therefore pursuant to section 319F-3(b) of the Act, I have determined that the risk that the spread of H1N1 swine influenza viruses and resulting disease constitutes a public health emergency. In order to clarify that the Original Declaration applies to H1N1 swine flu influenza, as well as other influenza strains which originate from animals and which have pandemic potential, the Original Declaration, is hereby amended as follows:

Strike the current section II, "Category of Disease," in its entirety and replace as follows:

II. Category of Disease (As Required by Section 319F-3(b)(2)(A) of the Act)

The category of disease, health condition, or threat to health for which I am recommending the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian H5N1 influenza A viruses or other animal influenza A viruses (including, but not limited to, H1N1 swine influenza) that are, or may be capable of developing into, a pandemic strain.

In section VIII, strike the section in its entirety and replace it with the following: "This Declaration has been amended. The Original Declaration was published in the **Federal Register** at 73 FR 61861. This is the first amendment to the Original Declaration. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-3(b)(4) of the Act."

All other provisions of the Original Declaration remain in full force.

This amendment to the Declaration will be published in the **Federal Register**, pursuant to section 319F-3(b)(4) of the Act.

Dated: June 11, 2009.

Kathleen Sebelius,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM): Amended Notice

AGENCY: National Institute of Environmental Health Sciences

(NIEHS), National Institutes of Health (NIH).

ACTION: Availability of public video casting of meeting.

SUMMARY: This notice announces the availability of public video casting of the SACATM meeting on June 25-26, 2009. The meeting will be held at the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, VA 22203 and video cast through a link on the SACATM Web site (<http://ntp.niehs.nih.gov/go/7441>). Information regarding the meeting was announced in the **Federal Register** (74 FR 19562) published on April 29, 2009 and available on the NTP Web site (<http://ntp.niehs.nih.gov/go/32822>).

DATES: The SACATM meeting will be held on June 25 and 26, 2009. The meeting is scheduled from 8:30 a.m. to approximately 5:30 p.m. on June 25 and 8:30 a.m. until adjournment on June 26, 2009.

ADDRESSES: The SACATM meeting will be held at the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, VA 22203 [hotel: (703) 528-6000].

SUPPLEMENTARY INFORMATION:

Archived Video of the Meeting

Following the meeting, the archived video of the meeting will be available on the SACATM meeting Web page (<http://ntp.niehs.nih.gov/go/7441>).

Dated: June 12, 2009.

John R. Bucher,
Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of the Community Healthy Marriage Initiative—Impact Evaluation—Wave 2.

OMB No.: 0970-0322.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is conducting a demonstration and evaluation called the Community Healthy Marriage Initiative (CHMI). Demonstration programs have been funded through Healthy Marriage and Responsible Fatherhood grants authorized under section 403(a)(2) of the Social Security Act to support healthy marriage directly and to