

**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

encourage community changes that increase support for healthy marriages and improve child and family wellbeing.

The objective of the evaluation is to: (1) Assess the implementation of community interventions designed to provide marriage education by examining the way the projects operate and by examining child support outcomes among low-income families in the community; and (2) evaluate the

community impacts of these interventions on marital stability and satisfaction, child well-being and child support outcomes among low income families.

The purpose of this information collection is to conduct a follow-up survey of respondents from Wave 1 who live in the communities where CHMI demonstrations are operating, and a survey of CHMI program participants. The impact evaluation will assess the

effects of community healthy marriage initiatives by comparing family and child well-being outcomes in the CHMI communities with similar outcomes in comparison communities that are well matched to the demonstration project sites.

*Respondents:* Community members and program participants in CHMI treatment and comparison communities.

#### ANNUAL BURDEN ESTIMATE

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per respondent	Estimated annual burden hours
Wave 2 Survey .....	4,120	1	.75	3,090

Estimated Total Annual Burden Hours: 3,090.

#### Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: June 11, 2009.

**Seth F. Chamberlain,**

*OPRE Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

[30Day-09-09AN]

##### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

##### Proposed Project

National Youth Physical Activity and Nutrition Study (NYPANS)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

##### Background and Brief Description

The prevalence of obesity among adolescents aged 12 to 19 more than tripled in the past 20 years, increasing from 5% in 1980 to 17.6% in 2006. Obese young people are more likely than children of normal weight to become overweight or obese adults, and are therefore more at risk for associated adult health problems, including heart disease, type 2 diabetes, stroke, several

types of cancer, and osteoarthritis. However, healthy lifestyle habits, including healthy eating and physical activity, can lower the risk of becoming obese and developing related diseases.

CDC proposes to conduct a study involving a nationally representative sample of students attending public and private schools in grades 9-12. CDC will collect information from students in Spring 2010. The primary information collection will include a paper-and-pencil survey, a standardized protocol to measure height and weight, and telephone interviews to elicit 24-hour dietary recalls among a subsample of respondents. Information supporting the study also will be collected from school administrators and teachers.

The study will: (1) Provide nationally representative data on behaviors and behavioral determinants related to physical activity and nutrition; (2) provide data to help improve the clarity and strengthen the validity of questions on the Youth Risk Behavior Survey (OMB No. 0920-0493, exp. 11/30/2011), which has been conducted biennially since 1991; and (3) improve understanding of the associations among behaviors and behavioral determinants related to physical activity and nutrition, and their association with body mass index.

Study results will be used to develop more effective interventions for stemming the increase of obesity among adolescents, and will have implications for policy and program development for obesity prevention programs.

There are no costs to respondents except their time. The total estimated burden hours are 7,781.