

TRANSACTION GRANTED—EARLY TERMINATION—Continued

ET date	TRANS No.	ET req. status	Party name
29-MAY-09 .....	20090442	G	Eastern Financial Florida Credit Union.
		G	Eastern Financial Florida Credit Union.
		G	John C. Malone.
		G	Liberty Global, Inc.
01-JUN-09 .....	20090454	G	Liberty Global, Inc.
		G	GlaxoSmithKline plc.
	20090473	G	Stiefel Laboratories, Inc.
		G	Stiefel Laboratories, Inc.
	20090480	G	Mr. James Laurence Balsillie.
		G	Mr. Jerry Moyes.
		G	Coyotes Hockey, LLC.
		G	Green Plains Renewable Energy, Inc.
02-JUN-09 .....	20090482	G	RBF Acquisition II, LLC.
		G	RBF Acquisition II, LLC.
	20090488	G	Lime Rock Partners V, LP.
		G	Allis-Chalmers Energy Inc.
	20090465	G	Allis-Chalmers Energy Inc.
		G	Aurora Resurgence Fund (C) L.P.
		G	Norwood Promotional Products Holdings, Inc.
		G	Norwood Promotional Products, Inc.
05-JUN-09 .....	20090466	G	United Technologies Corporation.
		G	Watsco, Inc.
	20090489	G	Watsco, Inc.
		G	Watsco, Inc.
	20090497	G	United Technologies Corporation.
		G	Carrier Sales and Distribution, LLC.
		G	TC PipeLines, LP.
		G	TransCanada Corporation.
20090500	G	North Baja Pipeline, LLC.	
	G	BioMarin Pharmaceutical Inc.	
	G	Medicis Pharmaceutical Corporation.	
	G	Medicis Pediatrics, Inc.	
		G	Windstream Corporation.
		G	D&E Communications, Inc.
		G	D&E Communications, Inc.

**FOR FURTHER INFORMATION CONTACT:**  
Sandra M. Peay, Contact Representative, or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H-303, Washington, DC 20580, (202) 326-3100.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. E9-14919 Filed 6-24-09; 8:45 am]

**BILLING CODE 6750-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Pandemic Influenza Vaccines—Amendment**

**Authority:** 42 U.S.C. 247d-6d.

**ACTION:** Notice of third amendment to the January 26, 2007 Declaration under the Public Readiness and Emergency Preparedness Act, and Republication of the Declaration, as Amended.

**SUMMARY:** Amendment to declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide targeted liability protections for pandemic countermeasures based on the Acting Secretary’s determination, under section 319F-3(b) of the Act, that the risk that the spread of H1N1 swine influenza viruses (now known as 2009 H1N1 Influenza A, or 2009 H1N1 influenza) and resulting disease constitutes a public health emergency; and republication of the declaration to reflect the declaration in its entirety, as amended.

**DATES:** The third amendment and republication of the declaration are effective as of June 15, 2009.

**FOR FURTHER INFORMATION CONTACT:** RADM W.C. Vanderwagen, 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).

**HHS Secretary’s Amendment to the Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, and H9 Vaccines**

*Whereas*, on April 26, 2009, Acting Secretary Charles Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d) (“the Act”), that a public health emergency exists nationwide involving the Swine influenza A virus that affects or has significant potential to affect the national security (“2009 H1N1 influenza”);

*Whereas*, the World Health Organization has established a Pandemic alert phase 5 for the 2009 H1N1 influenza virus currently circulating worldwide;

*Whereas*, vaccination may be effective to protect persons from the threat of 2009 H1N1 influenza;

*Whereas*, Secretary Michael O. Leavitt issued a Declaration for the Use of the Public Readiness and Emergency Preparedness Act dated January 26, 2007 (“Original Declaration”), as amended on November 30, 2007 and

October 17, 2008 with respect to certain avian influenza viruses; minor modifications are necessary to correct previous, minor, editorial errors; and republication of the Original Declaration, as amended, in its entirety is necessary for clarity;

*Whereas*, the findings made by the Secretary in the Original Declaration, as amended, continue to apply generally, and apply with equal force as to the 2009 H1N1 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, and use of additional covered countermeasures with respect to the category of disease and population described in sections II and IV of the Original Declaration, as amended, and as hereby further 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, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV of the Original Declaration, as amended, and as hereby further 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 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 2009 H1N1 influenza and resulting disease constitutes a public health emergency. In order to extend the Original Declaration, as amended, to apply to the 2009 H1N1 influenza and to correct previous, minor, editorial errors, the Original Declaration, as amended, is hereby further amended and republished as follows:

In the title, strike “and H9” and insert “H9, and 2009 H1N1”.

In the first “whereas” clause, first sentence, strike “(H5N1). H7 and H9 vaccines” and insert “H5N1, H7, and H9”.

After the fourth “whereas” clause, insert a new recital as follows:

Whereas, on April 26, 2009, Acting Secretary Charles E. Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d), that a public emergency exists nationwide involving the 2009 H1N1 influenza virus that affects or has significant potential to affect the national security (now called “2009 H1N1 influenza”);

In the ninth “whereas” clause, insert “;” after “IV”; strike “of the Original Declaration, as amended.”; insert “;” after “VI”; and strike “of the Original Declaration.”;

In the “therefore” clause concluding the recitals, strike the period and insert “, and that the 2009 H1N1 influenza constitutes a public health emergency.”.

In section I, second paragraph, first sentence, strike all after “influenza A” and insert “H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines and any associated adjuvants.”.

In section I, second paragraph, second sentence, strike all after “influenza A” and insert “H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines used and administered in accordance with this declaration.”.

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 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 following exposure to the virus with (1) highly pathogenic avian influenza A (H5N1, H2, H6, H7, or H9) virus; or (2) 2009 H1N1 influenza.

In section III, strike the period and insert “; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013.”

In Section VIII, strike the section in its entirety and replace it with the following:

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was published on January 26, 2007 and amended on November 30, 2007 to add H7 and H9 vaccines and on October 17, 2008 to add H2 and H6 vaccines. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-2(b)(4) of the Act.

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

## **Republication of HHS Secretary's Original Declaration, as Amended, for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H9, and 2009 H1N1 Vaccines**

To the extent any term of the original January 27, 2007 Declaration or any amendment thereto is inconsistent with any provision of this republished Declaration, the terms of this republished Declaration are controlling.

## **HHS Secretary's Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H9, and 2009 H1N1 Vaccines**

Whereas highly pathogenic avian influenza A H5N1, H7, and H9 have spread by infected migratory birds and exports of live poultry from Asia through Europe and Africa since 2004, and could spread into North America in 2006 or later, and have caused disease in humans with an associated high case fatality upon infection with this virus;

Whereas, the H2 class of influenza viruses, which caused the human influenza pandemic of 1957 and reappeared recently in U.S. animals including swine, is viewed as a likely candidate to re-evolve into an influenza strain capable of causing a pandemic of human influenza;

Whereas, the H6 class of influenza viruses, which appeared recently in animals including domestic fowl, is viewed as a likely candidate to evolve into an influenza strain capable of causing a pandemic of human influenza;

Whereas, an H5N1, H2, H6, H7 or H9 avian influenza virus may evolve into strain capable of causing a pandemic of human influenza;

Whereas, on April 26, 2009, Acting Secretary Charles E. Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d), that a public health emergency exists nationwide involving the Swine Influenza A virus that affects or has significant potential to affect the national security (now called “2009 H1N1 influenza”);

Whereas, the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F-3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d-6d(b)) (“the Act”);

Whereas, immunity under section 319F-3(a) of the Act should be available to governmental program planners for distributions of Covered Countermeasures obtained voluntarily, such as by (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles;

Whereas, the extent of immunity under section 319F-3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such covered countermeasures;

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, and use of medical countermeasures with respect to the category of disease and population described in section II and IV 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;

Whereas, in accordance with section 319F-3(b)(6) of the Public Health Service Act (42 U.S.C. 247d-6d(b)) (“the Act”), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV below, and have found it desirable to encourage such activities for the Covered Countermeasures;

Therefore, pursuant to section 319F-3(b) of the Act, I have determined there is a credible risk that the spread of avian influenza viruses and resulting disease could in the future constitute a public health emergency, and that 2009 H1N1 influenza constitutes a public health emergency.

### **I. Covered Countermeasures (as Required by Section 319F-3(b)(1) of the Act)**

Covered Countermeasures are defined at section 319F-3(i) of the Act.

At this time, and in accordance with the provisions contained herein, I am recommending the manufacture, testing, development, distribution, dispensing; and, with respect to the category of disease and population described in sections II and IV, below, the administration and usage of the pandemic countermeasure influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 Vaccines and any associated adjuvants. The immunity specified in section 319F-3(a) of the Act shall only be in effect with respect to: Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for pandemic countermeasure influenza A H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines used and administered in accordance with this declaration. In accordance with section 319F-3(b)(2)(E) of the Act, for governmental program planners, the immunity specified in section 319F-3(a) of the Act shall be in effect to the extent they obtain Covered Countermeasures through voluntary means of distribution, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles. For all other covered persons, including other program planners, the immunity specified in section 319F-3(a) of the Act shall, in accordance with section 319F-3(b)(2)(E) of the Act, be in effect pursuant to any means of distribution.

This declaration shall subsequently refer to the countermeasures identified above as Covered Countermeasures.

This declaration shall apply to all Covered Countermeasures administered or used during the effective time period of the declaration.

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

The category of disease 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 following exposure to the virus with (1) highly pathogenic avian influenza A (H5N1, H2, H6, H7, or H9) virus; or (2) 2009 H1N1 influenza.

### **III. Effective Time Period (as Required by Section 319F-3(b)(2)(B) of the Act)**

The effective period of time of this Declaration commences on December 1, 2006 and extends through February 28, 2010; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013.

### **IV. Population (as Required by Section 319F-3(b)(2)(C) of the Act)**

Section 319F-3(a)(4)(A) confers immunity to manufacturers and distributors of the Covered Countermeasure, regardless of the defined population.

Section 319F-3(a)(3)(C)(i) confers immunity to covered persons who could be program planners or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the declaration administers or uses the Covered Countermeasure and is in or connected to the geographic location specified in this declaration, or the program planner or qualified person reasonably could have believed that these conditions were met.

The populations specified in this Declaration are the following: (1) All persons who use a Covered Countermeasure or to whom such a Covered Countermeasure is administered as an Investigational New Drug in a human clinical trial conducted directly by the Federal Government, or pursuant to a contract, grant or cooperative agreement with the Federal Government; (2) all persons who use a Covered Countermeasure or to whom such a Countermeasure is administered in a pre-pandemic phase, as defined below; and/or (3) all persons who use a Covered Countermeasure, or to whom such a Covered Countermeasure is administered in a pandemic phase, as defined below.

### **V. Geographic Area (as Required by Section 319F-3(b)(2)(D) of the Act)**

Section 319F-3(a) applies to the administration and use of a Covered Countermeasure without geographic limitation.

### **VI. Other Qualified Persons (as Required by Section 319F-3(i)(8)(B) of the Act)**

With regard to the administration or use of a Covered Countermeasure, Section 319F-3(i)(8)(A) of the Act defines the term “qualified person” as a licensed individual who is authorized to prescribe, administer, or dispense the countermeasure under the law of the State in which such Covered Countermeasure was prescribed,

administered or dispensed. Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: None.

#### VII. Additional Time Periods of Coverage After Expiration of Declaration (as Required by Section 319F-3(b)(3)(B) of the Act)

A. I have determined that, upon expiration of the applicable time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including the return of such product to the manufacturer, and for covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

B. The Federal Government shall purchase the entire production of Covered Countermeasures under the contracts specifically listed by contract number in section I for the stockpile under section 319F-2 of the Act, and shall be subject to the time-period extension of section 319F-3(b)(3)(C). Production under future contracts for the same vaccine will also be subject to the time-period extension of section 319F-3(b)(3)(C).

#### VIII. Amendments

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was published on January 26, 2007 and amended on November 30, 2007 to add H7 and H9 vaccines and on October 17, 2008 to add H2 and H6 vaccines. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-2(b)(4) of the Act.

#### IX. Definitions

For the purposes of this declaration, “pre-pandemic phase” means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas. For the purposes of this declaration, “pandemic phase” means the following stages, as defined in the

National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Dated: June 15, 2009.

**Kathleen Sebelius**,  
Secretary.

#### Appendix

##### I. List of U.S. Government Contracts—Covered H5N1 Vaccine Contracts [January 26, 2007]

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI-0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

[60 Day-09-09BX]

##### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects.

Alternatively, to obtain a copy of the data collection plans and instrument, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

#### Proposed Project

*Clostridium difficile* Infection (CDI) Surveillance—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments of the impact of CDI in the United States. *C. difficile* is an anaerobic, spore-forming, gram positive bacillus that produces two pathogenic toxins: A and B. CDI ranges in severity from mild diarrhea to fulminant colitis and death. Transmission of *C. difficile* occurs primarily in healthcare facilities, where environmental contamination by *C. difficile* spores and exposure to antimicrobial drugs are common. No longer limited to healthcare environments, community-associated CDI is the focus of increasing attention. Recently, several cases of serious CDI have been reported in what have been considered low-risk populations, including healthy persons living in the community and peri-partum women.

For this proposed data collection, the surveillance population will consist of persons residing in the catchment area of the participating Emerging Infections Program (EIP) sites. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing