substitutes for bulk de-icing salt to melt snow and ice. The relevant geographic markets in which to assess the impact of the proposed Acquisition are the states of Maine and Connecticut.

The relevant markets are highly concentrated. ISCO and Morton are the two principal bidders in the states of Maine and Connecticut for the sale and delivery of bulk de-icing salt. Post acquisition, the combined entity will have a market share exceeding 70 percent in both Maine and Connecticut. Post-merger HHIs for Maine and Connecticut are 5,142 and 5,834, and the acquisition will increase HHI levels by 1,914 and 2,642, respectively. These market concentration levels far exceed the thresholds set forth in the *Horizontal Merger Guidelines* and thus create a presumption that the proposed merger will create or enhance market power.

Entry into the relevant markets is difficult because, among other things, there is a lack of acceptable stockpile space along the coasts of Maine and Connecticut. As a result, new entry sufficient to achieve a significant market impact within two years is unlikely.

Finally, the Complaint alleges that the proposed Acquisition will reduce competition in the relevant markets by eliminating direct and substantial competition between ISCO and Morton, and by increasing the likelihood that ISCO would increase prices either unilaterally or through coordinated interaction with the few remaining firms in the relevant markets.

IV. The Consent Agreement

To preserve the competition that otherwise would be eliminated by the Acquisition, the proposed Consent Agreement requires ISCO to divest to Commission-approved buyers, Eastern Salt and Granite State, assets sufficient to enable these buyers to become viable competitors for the de-icing salt business in the relevant markets beginning with the 2010-2011 bidding cycle. ISCO will divest to Eastern Salt the Maine Divestiture Assets, including: 1) stockpile space in the state, 2) all associated handling and trucking contracts, and 3) a book of de-icing salt business for the 2009-2010 winter season. ISCO will divest to Granite State the Connecticut Divestiture Assets, including: 1) stockpile space in the state, 2) all associated handling and trucking contracts, 3) a book of de-icing salt business for the 2009-2010 winter season, and 4) a three-year supply of de-icing salt at a price that is no more than ISCO's costs.

The Commission has preliminarily determined that Eastern Salt is a well-qualified buyer of the Maine Divestiture Assets and is well situated to replace the competition Morton provided in the state. Eastern Salt is a family-owned company that has been a de-icing salt supplier in other geographic markets along the East Coast for roughly 60 years. Eastern Salt is a vertically-integrated supplier with a dependable, high-quality supply of de-icing salt. With the divested assets, Eastern Salt will be well positioned to compete for future business in Maine and to deliver salt to customers in a timely manner.

The Commission has preliminarily determined that Granite State is a well-qualified buyer of the Connecticut Divestiture Assets and is well situated to replace the competition Morton provided in the state. Granite State has experience supplying de-icing salt to customers in a number of states along the East Coast. The Consent Agreement requires ISCO to provide Granite State with a three-year supply of bulk de-icing salt at no more than ISCO's costs. The supply requirement will ensure that Granite State has a supply of salt in Connecticut during the 2010-2011 and 2011-2012 bid cycles while Granite State develops the necessary supply arrangements to serve Connecticut customers in subsequent years. With the divested assets, Granite State will be well positioned to compete for future business in Connecticut and to deliver salt to customers in a timely manner.

The proposed Consent Agreement requires that the divestitures occur no later than twenty (20) days after the Acquisition is consummated. However, if ISCO divests the assets to Eastern Salt or Granite State during the public comment period, and if, at the time the Commission decides to make the Order final, the Commission notifies K+S or ISCO that either purchaser is not an acceptable acquirer or that the asset purchase agreement with the Maine Purchaser or Connecticut Purchaser is not an acceptable manner of divestiture, then ISCO must immediately rescind the transaction in question and divest those assets to another buyer within six (6) months of the date the Order becomes final. At that time, Respondents must divest those assets only to an acquirer and in a manner that receives the prior approval of the Commission. The proposed Consent Agreement also enables the Commission to appoint a trustee to divest any assets identified in the Order that K+S or ISCO has not divested to satisfy the requirements of the Order.

The proposed Consent Agreement further requires K+S and ISCO to maintain the viability and marketability of the Maine Divestiture Assets and the Connecticut Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of those assets prior to divestiture.

In order to ensure that the Commission remains informed about the status of the divestitures, the proposed Consent Agreement requires K+S and ISCO to file reports with the Commission periodically until the divestitures are completed. Written reports describing how K+S and ISCO are complying with the Order must be filed one year after the Order becomes final and annually for the next three (3) years.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark

Secretary.

[FR Doc. E9–23826 Filed 10–2–09: 6:40 am]

BILLING CODE: 6750–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Vaccines—Amendment

Authority: 42 U.S.C. 247d–6d.

ACTION: Notice of first amendment to the June 15, 2009 Republished Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: Amendment to declaration issued on June 15, 2009 (74 FR 30294) 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 to add provisions consistent with other declarations issued under this authority that may facilitate vaccination campaigns, and republication of the declaration to reflect the declaration in its entirety, as amended.

DATES: The first amendment of the republished declaration issued on June 15, 2009 is effective as of September 28, 2009.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, 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).

HHS Secretary's Amendment to the June 15, 2009 Republished Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H9 and 2009–H1N1 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 (now called ''2009–H1N1 influenza'');

Whereas, on July 24, 2009, I renewed the determination by the Acting Secretary that a public health emergency exists nationwide involving the Swine influenza A virus (now called ''2009–H1N1 influenza'');

Whereas, the World Health Organization has established a Pandemic alert phase 6 for the 2009–H1N1 influenza virus currently circulating worldwide;

Whereas, vaccination may be effective to protect persons from the threat of pandemic influenza;

Whereas, provisions that appear in other declarations issued pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) may assist in vaccination efforts;

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;

Whereas, I amended the declaration on June 15, 2009 which was republished in its entirety;

Whereas, modifications are necessary to aid States, Tribes, localities and other entities in conducting vaccination campaigns to make this declaration consistent with other declarations issued pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), and to correct a previous, minor, editorial error;

Whereas, the findings I made in the declaration issued on June 15, 2009 continue to apply;

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 republished Original Declaration, 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 June 15, 2009 Republished Declaration, as hereby 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 June 15, 2009 Republished 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 aid States, Tribes, localities and other entities in vaccination campaigns, to make this Declaration consistent with other Declarations issued pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) and to correct a previous, minor, editorial error, the June 15, 2009 Republished Declaration, is hereby amended as follows:

In the title, add ''H7'' before ''or H9''.

After the fifth ''whereas'' clause, insert two new recitals as follows:

Whereas, on July 24, 2009, I renewed the determination by the Acting Secretary that a public health emergency exists nationwide involving the Swine influenza A virus (now called ''2009–H1N1 influenza virus'');

Whereas, vaccination may be effective to protect persons from the threat of pandemic influenza;

In section I, second paragraph, strike the second sentence, and insert after the first sentence: ''The immunity specified in section 319F–3(a) of the Act shall only be in effect with respect to: (1) 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, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the pandemic countermeasures following a declaration of an emergency, as defined in section IX below.

In section III, add a second paragraph as follows: ''With respect to Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, the effective period of time of this Declaration commences on the date of a declaration of an emergency and lasts through and includes the final day that the emergency declaration is in effect including any extensions thereof; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013.''

Section VI, strike the second sentence and insert after the first sentence: ''Additional persons who are qualified persons pursuant to section 319F–3(i)(8)(B) are the following: (1) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency, and (2) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization.''

After Section VII, insert new Section VIII as follows and renumber subsequent sections:

VIII. Compensation Fund

In addition to conferring immunity to manufacturers, distributors, and administrators of the Covered Countermeasures, the Act provides benefits to certain individuals who sustain a covered injury as the direct result of the administration of the Covered Countermeasure. The Countermeasure Injury Compensation Program (CICP) within the Health Resources and Services Administration (HRSA) administers the Act's compensation program. Information about the CICP is available at 1–888–275–4772 or *http://www.hrsa.gov/countermeasurescomp/default.htm.*

Section VIII, strike the first sentence and insert: ''The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 was published on January 26, 2007; amended on November 30, 2007 to add

H7 and H9 vaccines; amended on October 17, 2008 to add H2 and H6 vaccines; amended on June 15, 2009 to add 2009 H1N1 vaccines and republished in its entirety.''

Section IX, strike in its entirety, and insert: ''For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.* law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic Phase: 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.

Pre-pandemic Phase: 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.''

Appendix I, ''I. List of U.S Government Contracts—Covered H5N1 Vaccine Contracts,'' title, add '', H2, H6, H9, and 2009–H1N1'' after ''H5N1''; delete ''[January 26, 2007]'' and add to the end of the list, ''32. All present, completed and future Government H5N1, H2, H6, H9, and 2009–H1N1 vaccine contracts not otherwise listed.''

All other provisions of the June 15, 2009 Republished Declaration remain in full force.

Republication of HHS Secretary's June 15, 2009 Republished 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 June 15, 2009 Republished Declaration, as hereby amended, 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, H7, 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, on July 24, 2009, I renewed the determination by the Acting Secretary that a public health emergency exists nationwide involving the Swine influenza A virus (now called ''2009–H1N1 influenza virus'');

Whereas, vaccination may be effective to protect persons from the threat of pandemic 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 countermeasures 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: (1) 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, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the pandemic countermeasures following a declaration of an emergency, as defined in section IX below. 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.

With respect to Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, the effective period of time of this Declaration commences on the date of a declaration of an emergency and lasts through and includes the final day that the emergency declaration is in effect including any extensions thereof; 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: (1) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency, and (2) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization.

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. Compensation Fund

In addition to conferring immunity to manufacturers, distributors, and administrators of the Covered Countermeasures, the Act provides benefits to certain individuals who sustain a covered injury as the direct result of the administration of the Covered Countermeasure. The Countermeasure Injury Compensation Program (CICP) within the Health Resources and Services Administration (HRSA) administers the Act's compensation program. Information about the CICP is available at 1–888–275–4772 or *http://www.hrsa.gov/countermeasurescomp/default.htm.*

IX. Amendments

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 was published on January 26, 2007; amended on November 30, 2007 to add H7 and H9 vaccines; amended on October 17, 2008 to add H2 and H6 vaccines; amended on June 15, 2009 to add 2009 H1N1 vaccines and republished in its entirety. 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.

X. Definitions

For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic Phase: 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.

Pre-pandemic Phase: 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.

Dated: September 28, 2009.

Kathleen Sebelius,

Secretary.

Appendix

I. List of U.S. Government Contracts—Covered H5N1, H2, H6, H9, and 2009–H1N1 Vaccine Contracts

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
32. All present, completed and future Government H5N1, H2, H6, H9, and 2009–H1N1 vaccine contracts not otherwise listed.

[FR Doc. E9–23844 Filed 10–2–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-09–09CV]

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. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *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 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