VIII. Amendments

This declaration has not previously been amended. Any future amendment to this declaration will be published in the **Federal Register**, pursuant to section 319F–3(b)(4) of the Act.

IX. 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 Covered Countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: 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 an 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 smallpox countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) unless such declaration specifies otherwise.

Smallpox Countermeasure: Any vaccine; antiviral, other drug; or diagnostic or device to identify, prevent or treat smallpox or orthopoxvirus or adverse events from such countermeasures (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the FDCA; (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR Part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.

This 10th day of October, 2008.

Michael O. Leavitt,

Secretary of Health and Human Services.

Appendix I

List of U.S. Government Contract

Contract	Manufacturer	Product	Pub. L. 85–804 coverage*
HHSO100200700034C	Bavarian Nordic	MVA	No.
200–2002–00425	Aventis Pasteur	WetVax	Yes.
200–2002–00357	Cangene	VIG	Yes.
200–2002–00004	Acambis	ACAM 2000	Yes.
200–2008–24959	Acambis	ACAM 2000 warm-base	No.
797BPA0003	Gilead	Cidofovir	No.

* Status of indemnification coverage under Pub. L. 85–804 (An Act to authorize the making, amendment and modification of contracts to facilitate the national defense.)

[FR Doc. E8–24737 Filed 10–14–08; 4:15 pm]
BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Vaccine—Amendment

October 10, 2008.

AGENCY: Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice of amendment (to the January 26, 2007 Declaration under the Public Readiness and Emergency Preparedness Act, as amended on February 1, 2007).

SUMMARY: 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 a credible risk that avian influenza viruses spread and evolve into strains capable of causing a pandemic of human influenza.

DATES: This notice and the attached amendment are effective as of the date of signature of the declaration.

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 H5N1 Declaration for the Use of the Public Readiness and Emergency Preparedness Act Dated January 26, 2007

Whereas the January 26, 2007 declaration for H5N1 vaccine (''Original Declaration'') was amended on February 1, 2007 to add H7 and H9 vaccines and additional, minor modifications to that amendment are necessary to ensure internal, editorial consistency of the Original Declaration, as amended.

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 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 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 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 section II and IV 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 there is a credible risk that the spread of the H2 and H6 subtypes of avian influenza viruses and resulting disease could in the future constitute a public health emergency. In order to: (1) Reflect the addition of medical countermeasures specific to the H2 and H6 subtypes of influenza viruses; (2) specify the means of distribution pursuant to section 319F–3(b)(2)(E) of the Act for which immunity specified in section 319F–3(a) of the Act shall be in effect; (3) clarify the applicability of immunity for covered persons and qualified persons as those terms are defined in the Act and provided for in the Original Declaration, as amended; and (4) ensure internal, editorial consistency in the Original Declaration arising from the February 1, 2007 amendment, the Original Declaration, as amended, is hereby further amended as follows:

In the title, insert ''H2, H6, H7 and H9'' after ''H5N1'' and replace ''Vaccine'' with ''Vaccines'' to read: ''HHS Secretary's Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H7 and H9 Vaccines''.

In the second Whereas clause, insert ''H2, H6, H7 or H9'' after ''H5N1'', replace ''viruses'' with ''virus'', and replace ''strains'' with ''strain'' to read: ''Whereas an H5N1, H2, H6, H7 or H9 avian influenza virus * * *''.

Insert the following Whereas clauses after the first Whereas clause:

''*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;''

Insert the following Whereas clauses after the second Whereas clause:

''*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 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;''

In Section I, strike the entire section and replace it with the following:

''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 of the Original Declaration, the administration and usage of the pandemic countermeasure influenza A (H5N1) vaccine and H2, H6, H7, and H9 vaccines. 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) vaccine and H2, H6, H7 and H9 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.''

In Section II, insert ''H2, H6, H7 or H9'' following ''H5N1.'' to read ''* * * highly pathogenic avian influenza A (H5N1, H2, H6, H7 or H9) virus * * *''.

In Section VIII, strike the section in its entirety and replace it with the following: ''This Declaration has been amended twice. The Original Declaration was published in the **Federal Register** at 72 FR 4710. The first amendment to the Original Declaration was published in the **Federal Register** at 72 FR 67731. This is the second 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.

This 10th day of October, 2008.

Michael O. Leavitt,

Secretary of Health and Human Services.

Appendix I

List of U.S. Government Contracts

Contract	Manufacturer	Covered countermeasure	Pub. L. 85–804 Coverage*
HHSN266200700005C	St. Jude Children's Research Hospital	H5N1, H2, H6, H7, H9	No.

[FR Doc. E8–24736 Filed 10–14–08; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–063–A]

Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) Stakeholders' Meeting

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Public Meeting and availability for Public Comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting and request for public comment on the Fire Fighter Fatality Investigation and Prevention Program (FFFIPP).

Public Meeting Time and Date: 10 a.m.–5 p.m., CST, November 19, 2008.

Place: Crowne Plaza Hotel, Chicago O'Hare, 5440 North River Road, Rosemont, Illinois 66018.

Purpose of Meeting: The public meeting will seek stakeholder input on the progress and strategic goals of the NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) to ensure that the program is meeting the needs of the stakeholders, and to identify ways in which the program can be improved to increase its impact on the safety and health of fire fighters across the United States. NIOSH will compile and consider all comments received at the meeting and through the NIOSH Docket Office and use them in making decisions on how to proceed with the FFFIPP.

Status: This meeting is hosted by NIOSH and will be open to the public, limited only by the space available. The meeting room will accommodate approximately 75 people.

Interested parties should make hotel reservations directly with the Crowne Plaza Hotel, telephone (847) 671–6350 or (800) 972–2494 and reference the NIOSH FFFIPP Stakeholders Meeting. Interested parties should confirm their attendance to this meeting by completing a registration form on the NIOSH Web site: *http://www.cdc.gov/niosh/fire/2008PublicMeetingRegistration.html*

Format of Meeting: The NIOSH Acting Director, Dr. Christine Branche, will provide opening remarks, followed by NIOSH presentations that provide an overview of the Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) and summary of Program changes and improvements since March 2006. NIOSH will present and make available for stakeholder input a set of draft Strategic Goals for FFFIPP for stakeholder consideration and comment. Stakeholders who have requested an opportunity to speak prior to the meeting will present suggestions for enhancing the impact of the program and future directions. An opportunity to make oral presentations will be provided to all interested parties, given time on the agenda. Presentations will be limited to 10 minutes. The meeting will end with an interactive session providing the opportunity for clarification of stakeholder comments.

Requests to make presentations at the meeting should be made by e-mail to Paul Moore, Chief, Fatality Investigations Team, e-mail *PMoore@cdc.gov*, telephone (304) 285–6016 or Matt Bowyer, General Engineer, e-mail *MBowyer@cdc.gov*, telephone (304) 285–5991, facsimile (304) 285–5774, before November 10, 2008. All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, and a brief summary of the presentation. After reviewing the requests for presentation, NIOSH FFFIPP staff will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order.

Written comments without an oral presentation are also encouraged, and should be submitted to the NIOSH Docket Office as outlined in the next section.

Written comments on the usefulness of the FFFIPP and products for improving fire fighter safety and health, suggestions for enhancing the impact of the program, and comments on the draft FFFIPP strategic and programmatic goals may be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, Mailstop C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533–8303, facsimile (513) 533–8285. Comments may also be submitted via e-mail to *niocindocket@cdc.gov.* All electronic comments should be formatted as Microsoft Word. Comments should be submitted to NIOSH no later than December 19, 2008, and should