TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting ..	6,000	0.5	45/60	2,250
Total	.....	.....	.....	1,138,230

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

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

ACTION: Notice.

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 influenza diagnostics, personal respiratory protection devices, and respiratory support devices based on a credible risk that an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

DATES: This notice and the attached declaration 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).

SUPPLEMENTARY INFORMATION: Highly pathogenic avian influenza A H5N1 viruses have been spread by infected migratory birds and exports of poultry or poultry products from Asia through Europe and Africa since 2003, and could spread into North America in 2008 or later, and have caused disease in humans, with over 60% of infected people dying from H5N1. In addition to H5N1, other animal influenza A viruses have also caused disease in humans, including H2N2, H7N7, H7N2, and H9N2 influenza A viruses, and also pose a pandemic threat. Section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), which was enacted by the Public Readiness and Emergency Preparedness Act, is intended to alleviate certain liability concerns associated with pandemic countermeasures, and, therefore, ensure that the countermeasures are available and can be administered in the event an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

HHS Secretary's Declaration for the Use of the Public Readiness and Emergency Preparedness Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices

Whereas highly pathogenic avian H5N1 influenza A viruses have spread, through various mechanisms, from Asia through Europe and Africa since 2003 and have caused disease in humans with an associated high case fatality. The real possibility that these viruses could be spread into North America exists as well as the possibility that these H5N1 viruses could participate directly or indirectly in development of a human pandemic strain;

Whereas other animal influenza viruses such as H2N2, H7N2, H7N7 and H9N2 viruses have also caused illness among humans and pose a pandemic threat;

Whereas avian H5N1 or other influenza A viruses might evolve into strains capable of causing a pandemic of human influenza;

Whereas there are countermeasures to identify, reduce exposure to, or support patients infected by highly pathogenic avian H5N1 influenza A viruses, other animal influenza viruses that pose a pandemic threat, or pandemic influenza in humans;

Whereas such countermeasures that currently exist or may be the subject of research and development include diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza; personal respiratory protection devices to reduce exposure to avian or other animal influenza A viruses; and respiratory support devices to support patients infected by avian or other animal influenza A viruses;

Whereas such countermeasures may be used and administered in accordance with Federal contracts, cooperative agreements, grants, interagency agreements, and memoranda of understanding, and may also be used and administered at the Regional, State, and local level in accordance with the public health and medical response of the Authority Having Jurisdiction;

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, 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 such 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; 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 below, 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 this declaration;

Therefore, pursuant to section 319F–3(b) of the Act, I have determined there is a credible risk that the spread of avian and other influenza viruses that pose a pandemic threat and resulting disease could in the future constitute 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 manufacturing, clinical testing, development, and distribution; and, with respect to the category of disease and population described in sections II and IV below, the administration and usage of pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices, as defined in section IX of this declaration. 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 involving countermeasures that are 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 Covered Countermeasure 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 period of the declaration.

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 that are, or may be capable of developing into, a pandemic strain.

III. Effective Time Period (as required by section 319F–3(b)(2)(B) of the Act)

With respect to Covered Countermeasures administered and used in accordance with present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding, the effective period of time of this Declaration commences on signature of the declaration and extends through December 31, 2015.

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.

IV. Population (as required by section 319F–3(b)(2)(C) of the Act)

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

Section 319F–3(a)(3)(C)(i) of the Act confers immunity to covered persons who may be a program planner or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the declaration uses the Covered Countermeasure or has the Covered Countermeasure administered to him 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 all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the Federal government or pursuant to a contract, grant, or cooperative agreement with the Federal government; (2) any person who receives a Covered Countermeasure from, or otherwise uses a Covered Countermeasure under direction from, a persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) any person who receives a Covered Countermeasure from, or otherwise uses a Covered Countermeasure under direction from, a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized under an Emergency Use Authorization; and (4) any person who receives a Covered Countermeasure in human clinical trials being conducted directly by the Federal government or pursuant to a contract, grant, or cooperative agreement with the Federal government.

V. Geographic Area (as required by section 319F–3(b)(2)(D) of the Act)

Section 319F–3(a) of the Act 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 Covered 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)

I have determined that, upon expiration of the 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 and 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.

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 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 Influenza Diagnostics: means diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (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.

Pandemic Influenza Personal Respiratory Protection Devices: means personal respiratory protection devices for use by the general public to reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as an influenza pandemic, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (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.

Pandemic Influenza Respiratory Support Devices: means devices to support respiratory function for patients infected with highly pathogenic influenza A H5N1 viruses or other influenza viruses that pose a pandemic threat when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (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.

Dated: December 17, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–30510 Filed 12–18–08; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the NTP Board of Scientific Counselors

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Meeting announcement and request for comments.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (NTP BSC). The NTP BSC is a federally chartered, external advisory group composed of scientists from the public and private sectors that provides primary scientific oversight to the NTP and evaluates the scientific merit of the NTP's intramural and collaborative programs.

DATES: The NTP BSC meeting will be held on February 24, 2009. The deadline for submission of written comments is February 6, 2009, and for pre-registering to attend the meeting, including providing notice of intent to present oral comments, is February 17, 2009. Persons needing interpreting services in order to attend should contact 301–402–8180 (voice) or 301–435–1908 (TTY). For other accommodations, contact 919–541–2475 or e-mail *niehsoeeo@niehs.nih.gov.* Requests should be made at least 7 days in advance of the event.