Contract	Manufacturer	Covered countermeasure	Pub. L. 85–804 coverage*
HHSO10020060000015I	Roche	Oseltamivir Phosphate (Tamiflu®)	No.
HHSO10020060000016I	GlaxoSmithKline	Zanamivir (Relenza®)	No.
HHSO100200600015I	Roche	Acquisiton of Tamiflu, 75 mg (state purchases).	No.
HHSO100200600016I	GlaxoSmithKline	Acquisiton of Relenza, 5 mg (state purchases).	No.
797HH7282	Roche	Oseltamivir, 75 mg (Tamiflu) (SNS)	No.
797HH7283	GlaxoSmithKline	Relenza (Zanamivir) 5 mg (SNS)	No.
797HH8113	GlaxoSmithKline	Relenza (Zanamivir) 5 mg (SNS)	No.
797HH8112	Roche	Oseltamivir 75 mg (Tamiflu) (SNS) Oseltamivir 45 mg (Tamiflu). Oseltamivir 30 mg (Tamiflu).	No.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

October 10, 2008.

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 *Botulism* countermeasures based on a credible risk that the threat of exposure to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source constitutes a public health emergency.

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).

HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Botulism Countermeasures

Whereas exposure to botulinum toxin(s) and the resulting disease(s) from manmade or natural sources may cause harm to the general population sufficient to constitute a public health emergency;

Whereas the Secretary of the Department of Homeland Security has determined that botulinum toxins present a material threat against the United States population sufficient to affect national security;

Whereas botulinum toxins are extremely potent and lethal;

Whereas there are covered countermeasures to treat, identify, or prevent adverse health consequences or death from botulinum toxins;

Whereas such botulism countermeasures, including antitoxins, for potential pre-exposure and for post-exposure prevention and treatment, diagnostics to identify such exposure, and additional countermeasures for treatment of adverse events arising from use of these botulism countermeasures exist, or may be the subject of research and/or development;

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 countermeasure; 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 botulinum toxin(s) and the resulting disease(s) from a

manmade or natural sources 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, and distribution of botulinum toxin countermeasures, as defined in section IX below; and, with respect to the category of disease and the population described in sections II and IV below, the administration and usage of botulinum toxin countermeasures.

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 Countermeasure is botulism resulting from exposure to botulinum toxin(s).

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 on 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 as persons who use the Covered Countermeasure or to whom such a Covered Countermeasure is administered, 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 are 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 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 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 the Covered Countermeasure without geographic limitation.

VI. 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 manufacturers 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 or Administration: 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.

Botulinum Toxin Countermeasure: Any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat botulinum toxin 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 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.

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 botulinum toxin 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.

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*
HHSO0100200600017C	Cangene	Heptavalent antitoxin	No.
03FED03828	PerImmune	Heptavalent antitoxin	No.
CDC 200–2003–01010	Cangene	Heptavalent antitoxin, Monovalent A	No.
CDC 200–2004–07625	Aventis Pasteur	Monovalent E	No.
CDC 200–2003–01052	Aventis Pasteur	Bivalent A and B	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.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

October 10, 2008.

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 Acute Radiation Syndrome countermeasures based on a credible risk that the threat of high dose radiation exposure following the deliberate detonation of a nuclear device, unintentional nuclear release, or other radiological events and the Acute Radiation Syndrome resulting from such exposures constitutes a public health emergency.

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: Acute Radiation Syndrome (ARS) is an acute illness that occurs when the entire body (or most of it) receives a high dose of radiation, usually over a short period of time. Radiation exposure can adversely affect a variety of cells, tissues, and organ systems, including the hematopoietic (or blood) system, the gastrointestinal (GI) tract, skin (cutaneous) system, and, at higher radiation levels, the lung or kidney and cerebrovascular/central nervous system (CNS).

HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Acute Radiation Syndrome

Whereas the risk of a deliberate detonation of a nuclear device in the United States intended to cause harm to the general population, unintentional radioactive release, or other radiological/nuclear events are considered a credible threat to public health;

Whereas the Secretary of the Department of Homeland Security has determined that radiological and nuclear agents present a material threat against the United States population sufficient to affect national security;

Whereas Acute Radiation Syndrome (ARS) resulting from such incidents could cause potentially severe adverse human health effects, including damage to the following organ systems: Hematopoietic (blood-forming),