TABLE 1—INFORMATION ON PARTICIPATING IN THE MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET [1]—Continued

	Dates	Electronic addresses	Addresses	Other information
View Web cast	May 20, 2015, from 10 a.m. to 1 p.m.	Individuals who are unable to attend the meeting in person, can register to view a live Web cast. You will be asked to indicate in your registration whether you plan to attend in person or via the Web cast.	.....	The Web cast will have closed captioning.
Request special accommodations due to disability.	Request at least 7 days before the meeting.	Graham Thompson, email: *Graham.Thompson@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	
Submit electronic or written comments.	Submit comments by June 30, 2015.	Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.	Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.	Identify your comments with the docket number listed in brackets in the heading of this document. We encourage you to submit electronic comments by using the Federal eRulemaking Portal.

[1] You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

IV. Comments and Transcripts

Regardless of attendance at the public meeting, interested persons may submit to FDA's Division of Dockets Management (see Addresses in table 1) either electronic or written comments on the interim assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs. You only need to send one set of comments. Identify the comments with the docket number provided in brackets in the heading of this document.

With respect to transcripts, please be advised that as soon as a transcript is available, it will be accessible at *www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm.*

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09300 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Therapeutics

ACTION: Notice of Declaration Under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is issuing a Declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to provide liability protection for activities related to Ebola Virus Disease Therapeutics consistent with the terms of the Declaration.

DATES: The Declaration is effective as of February 27, 2015.

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).

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (''PREP Act'') authorizes the Secretary of Health and Human Services (''the Secretary'') to issue a Declaration to provide liability immunity to certain individuals and entities (''Covered Persons'') against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (''Covered Countermeasures''), except for claims that meet the PREP Act's definition of willful misconduct. Using this authority, the Secretary is issuing a Declaration to provide liability immunity to Covered Persons for activities related to the Covered Countermeasures, Ebola Virus Disease Therapeutics as listed in Section VI of the Declaration, consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (''PHS'') Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new emergency authorities for dispensing approved products in emergencies and products held for emergency use.

PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

The Ebola virus causes an acute, serious illness that is often fatal. Since March 2014, West Africa has been experiencing the largest and most complex Ebola outbreak since the Ebola

virus was first discovered in 1976, affecting populations in multiple West African Countries and travelers from West Africa to the United States and other countries. The World Health Organization has declared the Ebola Virus Disease Outbreak as a Public Health Emergency of International Concern (PHEIC) under the framework of the International Health Regulations (2005).

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is separate and apart from a Declaration issued by the Secretary under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. Accordingly, in Section I, the Secretary determines that there is a credible risk that the spread of Ebola virus and the resulting disease may in the future constitute a public health emergency.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II, the Secretary states that she has considered these factors.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities''). In Section III, the Secretary recommends activities for which the immunity is in effect under the conditions stated in the Declaration, including the condition that the activities relate to clinical trials permitted to proceed after review by the Food and Drug Administration (FDA) that administer or use the Covered Countermeasure under an investigational new drug application (IND) and that are directly supported by the United States. The Secretary specifies that the term ''directly supported'' in this Declaration means that the United States has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing. This condition is intended to afford liability immunity only to activities related to clinical trials using the Covered Countermeasure currently being conducted in the United States and West Africa that are directly supported by the United States.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' In Section IV, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a State or local government, including an Indian Tribe; a person employed by the State or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other ''person'' can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department. Section V describes Covered Persons under the Declaration, including Qualified Persons.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. Section VI identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic

product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that: (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is exempted under the FD&C Act for use as an investigational drug or device that is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within ten years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists the Ebola Virus Disease Therapeutics that are Covered Countermeasures. Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products, or security countermeasures, or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.''

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to clinical trials that are permitted to proceed after FDA review, that administer or use the Covered Countermeasure under an IND, and that are directly supported by the United States, as described in Section III of this Declaration, through present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other Federal agreements or arrangements.

This limitation is intended to afford liability immunity to activities that are related to clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States. As stated in Section III of the Declaration, the term ''directly support'' means that the United States has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing. As of the date of this Declaration, those activities primarily are those with a direct connection to the conduct of clinical trials in the United States and West Africa, but this Declaration also would apply to use in qualifying clinical trials outside those areas.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, 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.

This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII, the Secretary states that the disease threat for which she recommends administration or use of the Covered Countermeasures is Ebola virus disease.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX, the Secretary defines ''Administration of a Covered Countermeasure:''

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by

physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a therapeutic, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X includes these statutory conditions in the Declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the Declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in West Africa. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI includes these statutory conditions in the Declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII identifies the effective time period. The effective time period commences at the start of clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States, as described in Section III of the Declaration. Liability immunity is afforded to claims arising from such administration or use of the Covered Countermeasures after that date that have a causal relationship with any of the Recommended Activities stated in this Declaration.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile under 42 U.S.C. 247d–6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the Declaration, plus the ''Additional Time Period''' described under section XIII of the Declaration.

Section XIII provides for twelve (12) months as the additional time period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any products obtained for the Strategic National Stockpile during the effective period of the Declaration.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes a Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. Section XIV, ''Countermeasures Injury Compensation Program'' explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify if countermeasures are administered or used outside the United States, only otherwise eligible individuals at American embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV, Amendments

The Secretary may amend any portion of a Declaration through publication in the **Federal Register**.

Declaration, Public Readiness and Emergency Preparedness Act Coverage for Ebola Virus Disease Therapeutics

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that the spread of Ebola virus and the resulting disease or conditions may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures under the conditions stated in this Declaration, including the condition that the activities relate to clinical trials permitted to proceed after review by the Food and Drug Administration (FDA) that administer or use the Covered Countermeasure under an investigational new drug application (IND) and that are directly supported by the United States. The term ''directly supported'' in this Declaration means that the United States has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2),(3),(4),(6),(8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. In addition, I have determined that the following additional persons are qualified persons: Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity to carry out clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States, as described in Section III of this Declaration.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are the following Ebola Virus Disease Therapeutics: ZMapp monoclonal antibody therapeutic.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States, as described in Section III of this Declaration, through present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other Federal agreements or arrangements.

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, 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.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is Ebola virus disease.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered

Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures begins on the effective date and extends for twelve (12) months from that date.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (''SNS'') during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes a Countermeasures Injury Compensation Program (''CICP'') to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration (''HRSA''), within the Department of Health and Human Services. Information about the CICP is available at the toll free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Any amendments to this Declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: April 9, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–09412 Filed 4–21–15; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Availability of the Department of Health and Human Services FY 2014 Service Contract Inventory

AGENCY: Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, Department of Health and Human Services.

ACTION: Notice of Public Availability of FY 2014 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Public Law 111–117), Department of Health and Human Services (HHS) is publishing this notice to advise the public of the availability of its FY 2014 Service Contract Inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2014. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf.* HHS has posted its inventory and a summary of the inventory on the HHS homepage at the following link: *http://www.hhs.gov/grants/servicecontracts/.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Lori Sakalos, Director in the HHS/Office of the Secretary, Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Office of Acquisition Policy at 202–690–6361 or *Lori.Sakalos@hhs.gov*.

Dated: April 16, 2015.

Angela Billups

Associate Deputy Assistant Secretary for Acquisition, Senior Procurement Executive, Assistant Secretary for Financial Resources, Office of the Secretary.

[FR Doc. 2015–09415 Filed 4–21–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI EDRN Review I.

Date: June 9, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Delia Tang, MD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, MD 20850, 240–276–6456 *tangd@mail.nih.gov.*

Name of Committee: National Cancer Institute Initial Review Group; NCI Subcommittee F-Institutional Training and Education.

Date: June 9, 2015.

Time: 11:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Timothy C. Meeker, Ph.D., MD, Scientific Review Officer, Resource and Training Review Branch, Division of