name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft revised Blueprint to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised Blueprint.

FOR FURTHER INFORMATION CONTACT: Janelle Derbis, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration 20 North Michigan Ave., Suite 510, Chicago, IL 60602, 312–596–6516.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of draft revisions to the ''FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics'' (draft revisions to the Blueprint). In addition to seeking comment on the draft revisions to the Blueprint, FDA expects the draft revisions to create important context for discussions at a public workshop on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of opioids) for health care providers. That workshop, which is scheduled for May 9–10, 2017, was previously announced in the **Federal Register** on April 18, 2017 (82 FR 18300).

I. Background

On July 12, 2012, FDA approved an ER/LA Opioid Analgesics REMS, including an FDA-created ''Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics.'' The goal of the REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications.

The ER/LA Opioid Analgesics REMS requires that training in the form of accredited continuing education be made available to health care providers who prescribe ER/LA opioid analgesics. The accredited continuing education must include all elements of the FDA Blueprint, which includes a basic outline and the core messages related to ER/LA opioid analgesics. FDA developed the Blueprint following extensive input from stakeholders and sought input on a draft version on November 7, 2011 (76 FR 68766), before approving it in 2012 as part of the ER/LA Opioid Analgesics REMS.

On May 3–4, 2016, FDA convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss whether this REMS assures safe use of these products; whether or not it is unduly burdensome to patient access to the drugs; and whether it (to the extent practicable) minimizes the burden to the health care delivery system (March 14, 2016, 81 FR 13372). FDA also sought input on possible modifications to the ER/LA Opioid Analgesic REMS, including expansion of the scope and content of prescriber training and expansion of the REMS program to include immediate release (IR) opioid analgesics. Advisory Committee members were in favor of modifying the REMS program to include the IR opioid analgesics as well as broadening the training program to include pain management. The majority of the members were in favor of a requirement for all prescribers to complete training. Many of the members recommended that the required training program be implemented through mechanisms outside the FDA REMS authority. The majority of members also stated that other health care providers involved in the management of pain should be included as a target audience for education, though they did not specify that the training should be mandatory for non-prescribing health care providers.

II. Potential Modifications to the FDA Blueprint

FDA is considering modifications to the existing Blueprint in light of recommendations from the May 2016 Advisory Committee meeting. The draft revisions to the Blueprint being made available pursuant to this notice would broaden the Blueprint to include information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). FDA intends to consider public input as it considers modifications to the ER/LA Opioid Analgesics REMS.

III. May 2017 Public Workshop

On April 18, 2017, FDA published a notice announcing a public workshop scheduled for May 9–10, 2017, to seek input on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of opioids) for health care providers. Through the public workshop, FDA hopes to obtain additional insight from a variety of stakeholders on how best to ensure that health care providers receive training in pain management and the safe use of opioids. The draft revisions to the Blueprint being made available at *https://www.fda.gov/Drugs/NewsEvents/ucm553931.htm* are intended to provide important context for the public workshop's discussion. However, the Blueprint itself will not be a discussion topic at the workshop. FDA intends to consider any comments submitted to this docket as it considers possible modifications to the ER/LA Opioid Analgesics REMS.

Dated: May 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09442 Filed 5–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamate) Countermeasures

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Secretary is issuing a declaration pursuant to section 319F–3 of the Public Health Service Act to

provide liability protections consistent with that authority for medical countermeasures against nerve agents and organophosphorus insecticides that result in organophosphorus poisoning and carbamate insecticides that result in carbamate poisoning.

DATES: The declaration is effective as of April 11, 2017.

FOR FURTHER INFORMATION CONTACT: George W. Korch Jr., Ph.D., Acting 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 the U.S. Department of Health and Human Services 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 this declaration for medical countermeasures against nerve agents and organophosphorus insecticides that result in organophosphorus poisoning and carbamate insecticides that result in carbamate poisoning. The purpose of issuing this declaration is to strengthen preparedness against these threats that pose an ongoing credible risk of a future public health emergency and does not indicate a change in threat information.

The declaration is published in full. We explain both the substantive and format changes in this supplementary section.

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 & 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 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.

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.[1] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act [2] 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. The declaration states in section I the Secretary's determination that there is a credible risk that the release of nerve agents or organophosphorus insecticides and the resulting organophosphorus poisoning or the release of carbamate insecticides and the resulting carbamate poisoning 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.[3] The declaration states these considerations in section II.

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).[4] The declaration states the Recommended Activities in section III.

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.[5] 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.'' [6] The declaration includes the statement that liability immunity is in effect for Recommended Activities in section IV.

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.[7] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[8]

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,

[1] 42 U.S.C. 247d–6d(b)(1).

[2] 42 U.S.C. 247d.

[3] 42 U.S.C. 247d–6d(b)(6).

[4] 42 U.S.C. 247d–6d(b)(1).

[5] 42 U.S.C. 247d–6d(b)(1).

[6] 42 U.S.C. 247d–6d(a)(1).

[7] 42 U.S.C. 247d–6d(i)(2).

[8] 42 U.S.C. 247d–6d(i).

affiliates, successors, and assigns of a manufacturer; [9]

A *distributor* means a person or entity engaged in the distribution of drugs, 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; [10]

A *program planner* means a state or local government, including a Native American 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.[11] 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.[12] 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.[13]

The declaration lists Covered Persons in section V to include 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.

The declaration also lists in section V Additional Covered Persons to include: (a) 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 the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; and, (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section 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 section 564, 564A, or 564B of the FD&C Act.[14]

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 [15] 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.[16]

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 [17] 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.[18]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act; [19] licensed under the PHS Act; [20] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[21] 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 [22] that is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or 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.

The declaration describes the Covered Countermeasures in Section VI as: Any antidote; any other drug; all components and constituent materials of these antidotes and other drugs; all devices and their constituent components used in the administration of these antidotes and other drugs; any diagnostic; or any other device to identify, prevent, or treat organophosphorus or carbamate poisoning or adverse events from such countermeasures.

The declaration also includes in section VI a statement referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained

[9] 42 U.S.C. 247d–6d(i)(4).

[10] 42 U.S.C. 247d–6d(i)(3).

[11] 42 U.S.C. 247d–6d(i)(6).

[12] 42 U.S.C. 247d–6d(i)(8).

[13] 42 U.S.C. 247d–6d(i)(5).

[14] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.

[15] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[16] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[17] 21 U.S.C. 321(g)(1), (h);42 U.S.C. 262(i).

[18] 42 U.S.C. 247d–6d(i)(1)(B),(c)(1)(B).

[19] 21 U.S.C. 301 *et seq.*

[20] 42 U.S.C. 262.

[21] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[22] 21 U.S.C. 355(i), 360j(g).

through a particular means of distribution.[23]

The declaration states in section VII that liability immunity is afforded to Covered Persons for Recommended Activities related to: (a) Present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other Federal agreements or activities directly conducted by the Federal Government; or (b) 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 Countermeasures to respond to an event covered by a declared emergency, including authorized activities that occur as part of the response before the formal declaration of an emergency. The declaration also provides in section VII definitions for ''Authority Having Jurisdiction'' and ''Declaration of an Emergency:''

i. The 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.

ii. A declaration of emergency means any 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 the Covered Countermeasures, with the exception of a Federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

Subsection (b) is intended to cover distribution, dispensing, administration, or use of the covered countermeasure under a formal government-authorized response to circumstances at any time those activities occur to respond to an event that gives rise to a declared emergency. Subsection (b) is not intended to be limited to cover those activities only after an emergency is formally declared and includes authorized activities that occur as part of the response before the formal declaration of an emergency. The Secretary recognizes that in emergency circumstances, distribution, dispensing, administration, or use of countermeasures may need to be expedient and may occur prior to a formal declaration of an emergency. This concern is particularly critical for the countermeasures covered by this declaration, where the Covered Countermeasures may need to be administered within minutes of exposure to a nerve agent to save lives. Thus, the Secretary is clarifying that coverage under subsection (b) is intended to cover any distribution, dispensing, administration, or use in accordance with the Authority Having Jurisdiction at any time that those activities address the emergency circumstances that gave rise to the declared emergency even if the activities occur prior to the declaration itself.

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 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.[24] The declaration states in section VIII that the category of disease, health condition, or threat for which the Secretary recommends administration or use of the countermeasures is organophosphorus or carbamate poisoning.

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. The declaration defines administration in section IX as: 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.

This definition of ''administration'' is intended to extend 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.[25] 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 vaccine, 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.

[23] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[24] 42 U.S.C. 247d–6d(b)(2)(A).

[25] 42 U.S.C. 247d–6d(a).

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.[26] 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. The declaration provides in section X 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.[27] We included these statutory conditions in the declaration section X 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.[28] The declaration states in section XI that there are no limitations on geographic area.

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.[29] We included these statutory conditions in the declaration section XI 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.[30]

The declaration states in section XII when liability immunity takes effect for different means of distribution within that time period.

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.[31] 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 section XII of the declaration, plus the ''Additional Time Period of Coverage'' described under section XIII of the declaration.

The declaration states in section XIII that the additional time period is twelve (12) months and also states that extended coverage applies to any products obtained for the Strategic National Stockpile during the effective period of the declaration. We included the statutory provision for clarity.

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.[32] 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,[33] and the statute.[34] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [35] 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. The declaration explains in section XIV, ''Countermeasures Injury Compensation Program'' 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**.[36] The declaration states in section XV that any amendments to this declaration will be published in the **Federal Register**.

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamate) Countermeasures

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 release of nerve agents or organophosphorus insecticides and the resulting organophosphorus

[26] 42 U.S.C. 247d–6d(b)(2)(C).
[27] 42 U.S.C. 247d–6d(a)(4).
[28] 42 U.S.C. 247d–6d(b)(2)(D).
[29] 42 U.S.C. 247d–6d(a)(4).
[30] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).
[31] 42 U.S.C. 247d–6d(b)(3).
[32] 42 U.S.C. 247d–6e.
[33] 42 CFR part 110.
[34] 42 U.S.C. 247d–6e.
[35] 42 U.S.C. 247d–6e(b)(4).
[36] 42 U.S.C. 247d–6d(b)(4).

poisoning or release of carbamate insecticides and the resulting carbamate poisoning 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, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

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: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; (c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

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: Any antidote; any other drug; all components and constituent materials of these antidotes and other drugs; all devices and their constituent components used in the administration of these antidotes and other drugs; any diagnostic; or any other device to identify, prevent, or treat organophosphorus or carbamate poisoning or adverse events from such countermeasures.

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:

(a) Present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other Federal agreements, or activities directly conducted by the Federal Government; or

(b) 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 Countermeasures to respond to an event covered by a declared emergency, including authorized activities that occur as part of the response before the formal declaration of an emergency.

i. The 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.

ii. A declaration of emergency means any 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 the Covered Countermeasures, with the exception of a Federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

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 organophosphorus or carbamate poisoning.

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 these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins on the date the response to an event covered by an emergency declaration begins, including authorized activities that occur as part of the response before the formal declaration of an emergency, and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2022, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (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 for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction 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 serious physical covered injury as the direct result of the administration or use of a Covered Countermeasure and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasure. 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: May 4, 2017.

Thomas E. Price,

Secretary.

[FR Doc. 2017–09455 Filed 5–9–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Institute of Child Health and Human Development Special Emphasis Panel; Learning Disabilities Research Centers.

Date: June 22–23, 2017.

Time: 7:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW., Washington, DC 20036

Contact Person: Marita R. Hopmann, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health & Human Development, 6710B Rockledge Drive, Bethesda, MD 20892, Phone: 301–435–6911, Email: *HopmannM@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Developmental Biology Subcommittee.

Date: July 24, 2017.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Chevy Chase, MD.

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892, 301–435–6878, *wedeenc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 4, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–09413 Filed 5–9–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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