remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.[25]

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on the date of this amended Declaration and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 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 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 the 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, 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)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: December 3, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–26977 Filed 12–8–20; 8:45 am]

BILLING CODE 4150–37–P

[25] 42 U.S.C. 247d–6d(b)(7) provides that ''[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Marburgvirus and/or Marburg Disease

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide limited immunity for activities related to countermeasures against marburgvirus and/or Marburg disease.

DATES: The Declaration is effective as of November 25, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, 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.

SUPPLEMENTARY INFORMATION: 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 manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

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 at 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 authorities for the emergency use of 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 (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 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, amended section 319F–3(i)(1)(D) of the PHS Act, to create a new category of covered countermeasures to the PREP Act, namely, respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

Marburg disease is a severe and often fatal illness in humans caused by marburgviruses, a group of filoviruses of the same family as ebolaviruses. Marburg disease is a highly virulent disease that causes hemorrhagic fever, with a case fatality rate of approximately 88 percent. Humans can become infected with marburgviruses, but it is largely unknown how marburgvirus transmits from its animal host to humans. For previous cases, unprotected contact with infected bat feces or aerosols was deemed the most likely route of infection. After the initial crossover of the virus from host animal to humans, transmission can occur through person-to-person contact. This may happen in several ways: Direct contact to droplets of body fluids from infected persons, or contact with equipment and other objects contaminated with infectious blood or tissues. The virus can spread between humans in close environments and through direct contact. A common route of infection is through nosocomial transmission.

Marburgvirus was first recognized in 1967, when outbreaks of hemorrhagic fever occurred simultaneously in laboratories in Marburg and Frankfurt, Germany and in Belgrade, Yugoslavia (now Serbia). Thirty-one people became ill, initially laboratory workers followed by several medical personnel and family members who had cared for them; seven deaths were reported. The first people infected had been exposed to imported African green monkeys or their tissues while conducting research.

From 1975–2014, there have been 10 reported outbreaks of Marburg disease, and all but one of these outbreaks had an apparent or suspected origin in Africa. These outbreaks have resulted in a total of 435 reported human cases of Marburg disease and 366 deaths among those reported cases; a case fatality rate of approximately of 84%. The recurrent but unpredictable and variable nature of Marburg disease outbreaks and the transmission profile makes marburgviruses a threat to the public health security of the American people, requiring vigilance and a continuing need for development of medical countermeasures. Similar to determinations and experiences with Ebola virus outbreaks, marburgvirus has been determined to have the potential to be a threat to US public health security.

Description of This Declaration by Section

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 constitute such an emergency.

This determination is separate and apart from the 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 of the Declaration, the Secretary determines that marburgviruses and Marburg disease are a credible risk such that Marburg disease or marburgviruses may in the future constitute a public health emergency.

Section II. Factors Considered by the Secretary

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 of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate 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 of the Declaration, the Secretary sets out the activities for which the immunity is in effect.

Section IV. Limited 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 of the Declaration, 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 the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: Manufacturers; re-packers; 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 authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered 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 of the Declaration describes Covered Persons, including Qualified Persons. The Declaration includes all persons and entities defined as Covered Persons under the PREP Act.

Section VI. Covered Countermeasures

As noted above, Section III of the Declaration describes the activities (referred to as ''Recommended Activities'') for which liability immunity is in effect. Section VI of the Declaration identifies the Covered 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; a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act; or respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS 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; approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS 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 subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and 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 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists countermeasures against marburgvirus and/or Marburg disease that are Covered Countermeasures under this declaration.

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, respiratory protective devices, 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 (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; 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 following a Declaration of an emergency.

Section VII defines the terms ''Authority Having Jurisdiction'' and ''Declaration of an emergency.'' We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

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 in the Declaration, 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 of the Declaration, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is Marburg disease caused by marburgviruses or virus mutating therefrom.

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 of the Declaration, the Secretary defines ''Administration of a Covered Countermeasure,'' as follows:

> 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 definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, 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.

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. Section X of the Declaration identifies 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.''

It should be noted that under the PREP Act, liability protection extends beyond the Population specified in the Declaration. Specifically, 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 of the Declaration 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, 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 of the Declaration 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 countries outside the U.S. 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 of the Declaration 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 of the Declaration extends the effective period for different means of distribution of Covered Countermeasures through August 1, 2025.

Section XIII. Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including accepting returns of Covered Countermeasures, 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

(SNS) under 42 U.S.C. 247d–6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continue 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'' described under Section XIII of the Declaration.

Section XIII of the Declaration provides for 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 product obtained for the SNS during the effective period of the Declaration.

Section XIV. Countermeasures Injury Compensation Program

Section 319F–4 of the PHS Act, 42 U.S.C. 247d–6e, authorizes the 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 align with the requirements for liability immunity provided under the PREP Act. Section XIV of the Declaration, ''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 that if countermeasures are administered or used outside the United States, only otherwise eligible individuals at United States 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

Section XV of the Declaration confirms that the Secretary may amend any portion of this Declaration through publication in the **Federal Register**.

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures Against Marburgvirus and/or Marburg Disease

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that Marburg disease and marburgviruses are a credible risk such that Marburg disease or marburgviruses may in the future constitute a public health emergency. This Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration.[1] This Declaration is a ''requirement'' under the PREP Act.

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.

[1] *See, e.g.,* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Nov. 24, 2020); Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Nov. 24, 2020); Advisory Opinion 20–03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Nov. 24, 2020); Advisory Opinion 20–04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Nov. 24, 2020). This is not to suggest that other PREP Act declarations should be construed in a manner contrary to the interpretation provided in the Advisory Opinions.

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, and 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; and (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 antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate Marburg disease, or the transmission of marburgviruses or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product, or countermeasures for adverse effects of these countermeasures, and

countermeasures that otherwise limit the harm caused by the health threat.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, respiratory protective devices 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

(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 following a Declaration of an emergency.

As used in this Declaration, the terms Authority Having Jurisdiction and Declaration of Emergency have the following meanings:

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 Marburg disease caused by marburgviruses or virus mutating therefrom.

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 through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through August 1, 2025.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) August 1, 2025, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 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 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 the 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, 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)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d

Dated: December 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26972 Filed 12–8–20; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Advisory Committee to the Director, National Institutes of Health, December 10, 12:00 p.m. to December 11, 05:00 p.m. National Institutes of Health, Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD, 20892 (Virtual Meeting) which was published in the **Federal Register** on 11/30/2020, 85 FR 76590.

The meeting notice is amended to change the meeting start time on December 10, 2020 from 12:00 p.m. to 12:30 p.m. The meeting is open to the public.

Dated: December 4, 2020.

Natasha M. Copeland,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–27055 Filed 12–8–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Three Vehicle Tracking Devices, a Satellite Device, an NFC Reader, and an NFC Keyring FOB

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of three vehicle tracking devices, a satellite device, a near field communication (NFC) reader, and an NFC keyring fob. Based upon the facts presented, CBP has concluded that the country of origin of the three vehicle tracking devices, the satellite device, and the NFC reader is Canada for purposes of U.S. Government procurement. The country of origin of the NFC keyring fob will be determined by the country of origin of the contactless integrated circuit (IC), which is usually Taiwan, but if unavailable, then either Thailand or Singapore will be the source country and the country of origin for purposes of U.S. Government procurement.

DATES: The final determination was issued on November 25, 2020. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within January 8, 2021.

FOR FURTHER INFORMATION CONTACT: Beth Jenior, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0347.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on November 25, 2020, pursuant to subpart B of part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of three vehicle tracking devices, one satellite device, one NFC reader, and one NFC keyring fob imported by Geotab USA, Inc. (Geotab), which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, Headquarters Ruling Letter H309128, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the country of origin of the three vehicle tracking devices, the satellite device, and the NFC reader is Canada for purposes of U.S. Government procurement. Regarding the NFC keyring fob, CBP concluded that the country of origin will be the country where the contactless integrated circuit is manufactured. In most cases, this will be Taiwan, but if the contactless integrated circuit cannot be sourced there, then it will be sourced from either Thailand or Singapore, and the corresponding sourcing country would then be the country of origin for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: November 25, 2020.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H309128

November 25, 2020

OT:RR:CTF:VS H309128 EGJ

CATEGORY: Origin

Mr. James Lay

Geotab USA, Inc.

770 E Pilot Rd., Suite A

Las Vegas, NV 89119

Re: U.S. Government Procurement; Country of Origin of Three Vehicle Tracking Devices, Satellite Device, NFC Reader, and NFC Keyring Fob; Substantial Transformation

Dear Mr. Lay

This is in response to your ruling request, dated February 6, 2020, requesting a final determination on behalf of Geotab USA, Inc. (''Geotab'') pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (''CBP'') Regulations (19 CFR part 177).

This final determination concerns the country of origin of three vehicle tracking devices, one satellite device, one near field communication (''NFC'') reader, and one NFC identification keyring fob. As a U.S. importer, Geotab is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and is entitled to request this final determination.

Facts

Geotab is a technology company which designs and imports vehicle tracking systems, and has submitted six different products for our review. The products' descriptions, pictures, and manufacturing processes are set forth below.

Product Descriptions

The first three products are telematics devices, which are designed to transmit vehicle tracking information over long distances. Specifically, the three products are: