TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 58.35(b)(7); Quality assurance unit	300	60.25	18,075	1	18,075
§ 58.185; Reporting of nonclinical laboratory study results	300	60.25	18,075	27.65	499,774
Total					517,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 58.29(b); Personnel	300	20	6,000	.21 (13 minutes)	1,260
§ 58.35(b)(1)–(6), and (c); Quality assurance unit	300	270.76	81,228	3.36	272,926
§ 58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	.09 (5 minutes)	1,620
§ 58.81(a)–(c); SOPs	300	301.80	90,540	.14 (8 minutes)	12,676
§ 58.90(c) and (g); Animal care	300	62.70	18,810	.13 (8 minutes)	2,445
§ 58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8	17,700
§ 58.107(d); Test and control article handling	300	1	300	4.25	1,275
§ 58.113(a); Mixtures of articles with carriers	300	15.33	4,599	6.8	31,273
§ 58.120; Protocol	300	15.38	4,614	32.7	150,878
§ 58.195; Retention of records	300	251.50	75,450	3.9	294,255
Total					786,308

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on an evaluation of the information collection, we are retaining the currently approved estimates. Our assumptions made regarding the time needed for the respective activities is based on our experience with the information collection and informal communications with respondents.

Dated: November 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26044 Filed 11–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to amend the Declaration for Countermeasures against Marburgvirus and/or Marburg Disease to cover both Ebolaviruses and Marburgviruses and republishes the declaration, as amended. The amended republished Declaration clarifies that the disease threat includes Ebolaviruses and Marburgviruses, updates the title of the Declaration, expands the Covered Countermeasures, and extends the effective time period.

DATES: The amendment is effective as of January 1, 2024.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *PREPAct@hhs.gov*.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the U.S. Department of Health and Human Services (the HHS 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. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, 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. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

The PREP Act Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease was first issued effective November 25, 2020. (85 FR 79198 (December 9, 2020)). The PREP Act Declaration for Ebola Virus Disease Vaccines was first issued December 3, 2014 (79 FR 73315 (Dec.10, 2014)), and amended December 3, 2015 (80 FR 76541 (Dec. 9, 2015)), December 3, 2016 (81 FR 89471 (Dec. 12, 2016)), and December 1, 2018 (84 FR 764 (Jan. 31, 2019)). The Declaration for Ebola Virus

Disease Therapeutics was issued effective February 27, 2015 (80 FR 22534 (April 22, 2015)), and amended February 27, 2015 (80 FR 76536 (December 9, 2015)), and December 1, 2018 (84 FR 757 (January 31, 2019)).

I am extending PREP Act Coverage for both Ebolaviruses and Marburgviruses due to the continued national security threat posed by these viruses. Ebolaviruses and Marburgviruses have the potential to cause significant morbidity and mortality during outbreaks. The risk of domestic cases is high due to ongoing outbreaks in other countries over the past decade. Development of and stockpiling vaccines, therapeutics, devices, and diagnostics for all species of both Ebolaviruses and Marburgviruses is needed for continued U.S. preparedness against the credible threat of a public health emergency due to outbreaks of these viruses.

I am amending the PREP Act Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease to cover countermeasures previously covered under the Declaration for Ebola Virus Disease Vaccines and the Declaration for Ebola Virus Disease Therapeutics due to the similarities of the viruses and the need to expand Covered Countermeasures against Ebola Disease to include all vaccines, diagnostics, and devices in addition to previously covered vaccines and therapeutics, and to cover these countermeasures when administered or used by an Authority Having Jurisdiction to respond to a declared emergency, in addition to previously covered activities directly supported by the United States. All previously Covered Countermeasures for Ebolavirus and distribution activities continue to be covered. This action has the effect of combining the three previous Declarations into one amended Declaration and makes PREP Act coverage for Ebolavirus countermeasures consistent with PREP Act coverage provided for other health threats, including Marburg, Smallpox, Pandemic Influenza, Anthrax, and Acute Radiation Syndrome and emerging infectious diseases such as COVID–19.[1] This amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the PREP Act Declaration for Ebola Virus Disease Vaccines and the PREP Act Declaration for Ebola Virus Disease Therapeutics. The Declarations for Ebola Virus Disease Vaccines and Ebola Virus Disease Therapeutics will expire under their own terms on December 31, 2023 and this amended Declaration becomes effective January 1, 2024, effectively replacing the three prior Declarations.

To be consistent with the most current World Health Organization International Classification of Diseases, the term Ebola disease or ''EBOD'' is used in this Declaration to refer to the disease, health condition, or threat to health that constitutes or may constitute a public health emergency. The term Marburg Disease or ''MARD'' is used in this Declaration to refer to the disease, health condition, or threat to health that constitutes or may constitute a public health emergency.[2]

Specifically, I am now amending the PREP Act Declaration Against Marburgvirus and/or Marburg Disease Countermeasures to: amend the title of the declaration to reflect that it covers Ebolaviruses and Marburgviruses; update Section I to identify the public health threat as arising from Ebolaviruses and Marburgviruses; update Section VI to amend the definition of Covered Countermeasures and to extend coverage to all vaccines, diagnostics, and devices for Ebolavirus in addition to vaccines and therapeutics; extend Section VII of the Declaration to provide coverage for Ebolavirus Countermeasures when administered or used by an Authority Having Jurisdiction to respond to a declared emergency; update Section VIII to amend the category of disease to be inclusive of Ebolaviruses and Marburgviruses; extend in Section XII the effective time period of the declaration through December 31, 2028; and republish the declaration in its entirety, as amended.

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

Description of This Amendment by Section

I am now amending the title of the Declaration to ''Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures against Ebolaviruses and/or Ebola Disease and Marburgvirus and/or Marburg Disease.''

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

I am amending Section I of the Declaration to update the determination of a public health emergency to state that the spread of Ebolaviruses and Marburgviruses, and any resulting diseases or conditions including EBOD and MARD, and any virus or disease subcategories of these, presents a credible risk of a future public health emergency. Continued coverage under the PREP Act, as provided in this Declaration, is intended to prepare for and mitigate that credible risk.

Section VI. Covered Countermeasures

I am amending Section VI of the Declaration to include any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to diagnose, mitigate, prevent, treat, cure, or limit EBOD, MARD, or the transmission of Ebolaviruses, 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.

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

I am amending Section VIII of the Declaration to update the category of disease to include any diseases or conditions including EBOD and MARD caused by Ebolaviruses and Marburgviruses, or any virus or disease subcategories of these or virus mutating therefrom.

Section XII. Effective Time Period

I am extending the effective time period for the Declaration through December 31, 2028.

Other conforming changes and technical corrections may be made throughout the Declaration for consistency and clarity.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease

To the extent any term previously included in the Declaration for Countermeasures Against Marburgvirus and/or Marburg Disease, the Declaration for Vaccines Against Ebola Virus Disease, or the Declaration for Therapeutics Against Ebola Virus Disease, including amendments, are inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that the spread of Ebolaviruses and Marburgviruses, and

[1] See *https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx.*

[2] See *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6637750/.*

any resulting diseases or conditions including Ebola Disease (EBOD) and Marburg Disease (MARD), and any virus or disease subcategories of these may in the future constitute a public health emergency. For the purposes of this Declaration, MARD is the illness resulting from infection by any virus of the *Orthomarburgvirus* genus. EBOD is the illness resulting from infection of any of the following virus species of the *Orthoebolavirus* genus:

- Bundibugyo virus
- Ebola virus
- Sudan virus
- Taï Forest virus
- Ebolaviruses with undefined pathogenicity in humans

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, 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: (1) any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to diagnose, mitigate, prevent, treat, cure, or limit the harm EBOD, MARD, or the transmission of Ebolaviruses, Marburgviruses, or a virus mutating therefrom, any device used in the administration of any such product, and all components and constituent materials of any such product; (2) any product to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (1); or (3) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (1) or (2).

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 following a 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 any diseases or conditions including EBOD and MARD caused by Ebolaviruses and Marburgviruses, or any virus or disease subcategories of these 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 other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through December 31, 2028.

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) December 31, 2028, 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 Strategic National Stockpile (SNS) during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes 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)

The December 3, 2014, Declaration under the PREP Act for Countermeasures Against Ebola Virus Disease Vaccines was first published on December 10, 2014, and amended and republished on December 9, 2015, December 12, 2016, and January 31, 2019. The republished amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the Declaration for Countermeasures Against Ebola Virus Disease Vaccines.

The February 27, 2015, Declaration under the PREP Act for Countermeasures Against Ebola Virus Disease Therapeutics was first published on April 22, 2015, and amended and republished on December 9, 2015, December 12, 2016, and January 31, 2019. The republished amended Declaration for Countermeasures Against Ebolavirus and/or Ebola Disease and Marburgvirus and/or Marburg Disease supersedes the Declaration for Countermeasures Against Ebola Virus Disease Therapeutics.

The November 25, 2020, Declaration under the PREP Act for Countermeasures Against Marburgvirus and/or Marburg Disease was published on December 9, 2020. This is the first amendment to and republication of the Declaration.

Any further amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: November 21, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–26075 Filed 11–24–23; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amend Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel T32 Diversity Training Grants, December 1, 2023, 11:00 a.m. to 1:00 p.m., National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 26, 2023, FR Document No. 2023–23751, 88 FRN 73863.

This notice is being amended to change the meeting title to ''The National Heart, Lung, and Blood Institute Special Emphasis Panel T32 Member Conflicts SEP.'' The meeting is closed to the public.

Dated: November 20, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–26020 Filed 11–24–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Customs Broker Permit User Fee Payment for 2024 and Announcement of eCBP Portal Payment Option

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

ACTION: General notice.

SUMMARY: This document provides notice to customs brokers that the annual user fee that is assessed for each