TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups	3,000	1	3,000	1.75	5,250
Customer comment cards/forms	1,500	1	1,500	0.25 (15 minutes)	375
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	20,000	1	20,000	0.33 (20 minutes)	6,600
Usability studies	1,100	1	1,100	1	1,100
Total					14,725

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

Based on a review of the information collection since our last request for OMB approval, we increased the number of respondents for focus groups, customer comment cards/forms, customer satisfaction surveys, and usability studies. This adjustment results in an overall burden increase of 6,234 hours.

Dated: November 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26043 Filed 11–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2894]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 27, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Good Laboratory Practice Requirements for Nonclinical Laboratory Studies—21 CFR Part 58

OMB Control Number 0910–0119—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification, and include information collection provisions.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

Description of Respondents: Respondents to the collection of information are sponsors of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by FDA.

In the **Federal Register** of August 8, 2023 (88 FR 53492), we published a 60-day notice soliciting comment on the proposed collection of information. One comment was received underscoring the critical nature of language translations in information exchange between international communities but did not suggest any modifications to our burden estimates.

We estimate the burden of this collection of information as follows:

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]

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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