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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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	No. of Respondents	No. 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	No. of Recordkeepers	No. 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

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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.

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