TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(8); adverse events	10	1	10	0.5	5
Total			569		1,789

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; FDA form	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	14	490	0.75	368
Total			766		3,128

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

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08300 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0075]

Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's good laboratory practice (GLP) regulations for nonclinical laboratory studies.

DATES: Submit either electronic or written comments on the collection of information by June 26, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov/.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov/* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov/.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0075 for ''Good Laboratory Practice Regulations for Nonclinical Studies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov/* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov/.* Submit both copies to the Division of Dockets Management. If you do not wish your 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.fda.gov/regulatoryinformation/dockets/default.htm.*

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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Good Laboratory Practice Regulations for Nonclinical 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 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.

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.

Recordkeeping is necessary to document the conduct of nonclinical laboratory studies of FDA-regulated products to ensure the quality and integrity of the resulting final study report on which a regulatory decision may be based. Written SOPs and records of actions taken are essential for testing facilities to implement GLP's effectively. Further, they are essential for FDA to be able to determine a testing facility's compliance with the GLP regulations in part 58.

In a notice of proposed rulemaking published in the **Federal Register** of August 24, 2016 (81 FR 58342), we proposed changes in our GLP regulations, including some of those listed in tables 1 and 2 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In response to requests, the comment period was extended to January 21, 2017 (81 FR 75351, October 31, 2016). In the interim, FDA is seeking an extension of OMB approval for the current regulations so that we can continue to collect information while the proposal is pending.

Description of Respondents: The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies.

FDA estimates 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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					517,849

[1] There are no capital costs or operating 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 (in hours)	Total hours
58.29(b); Personnel	300	20	6,000	0.21 (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	0.09 (5 minutes)	1,620
58.81(a)–(c); SOPs	300	301.8	90,540	0.14 (8 minutes)	12,676
58.90(c) and (g); Animal care	300	62.7	18,810	0.13 (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	251.5	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.

The annual burden for the information collection requirements in these regulations is estimated at 1,304,157 burden hours (517,849 plus 786,308 equals 1,304,157). The hours per response estimates are based on our experience with similar programs and information received from industry.

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08304 Filed 4–24–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (PRA).

DATES: Fax written comments on the collection of information by May 25, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For specific questions for FDA related to this document, contact JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION:

Institutional Review Boards—21 CFR 56.115—OMB Control Number 0910–0130—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes, and decisions made by the IRB, the number of votes on each decision for, against, and abstaining; the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations; and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

The recordkeeping requirement burden is based on the following: The burden for the paragraphs under 21 CFR 56.115 has been considered as one