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## 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 or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 invites 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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, 360(b), 360(e)) 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 good laboratory practices. 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.

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 Recordkeeping Burden<sup>1</sup>

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	0.21 (13 minutes)	1,260
58.35(b)(1)-(b)(6) and (c); Quality assurance	300	270.76	81,228	3.36	279,926
58.35(b)(7); Quality assurance	300	60.25	18,075	1	18,075
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
58.185; Nonclinical laboratory study results	300	60.25	18,075	27.65	499,774
58.195; Retention of records	300	251.5	75,450	3.9	294,255
Total					1,311,157

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 9, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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