



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 [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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0119. Also include the FDA 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, PRStaff@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 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, 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.

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 GLPs 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.

In the Federal Register of June 12, 2014 (79 FR 33755), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. On its own initiative, however, the Agency is now including two burden tables rather than only the one included in its 60-day notice. While this does not change the Agency's burden estimate, FDA believes that distinguishing between reporting elements and recordkeeping elements more clearly reflects the requirements associated with this information collection.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| 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 Burden¹

| 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 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 | 301.8 | 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.

Dated: September 23, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-22986 Filed 09/25/2014 at 8:45 am; Publication Date: 09/26/2014]