substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 11.100 | 4,500 | 1 | 4,500 | 1 | 4,500 |
| Total | | | | | 4,500 |

[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 | Annual frequency per recordkeeping | Total annual records | Hours per record | Total hours |
|---|---|---|---|---|---|
| 11.10 | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.30 | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.50 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| 11.300 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| Total | | | | | 280,000 |

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

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Governmentwide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–3465 Filed 2–15–11; 8:45 am]

**BILLING CODE 4160–01–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 (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 solicits comments on the good laboratory practice (GLP) for nonclinical laboratory studies regulations.

**DATES:** Submit either electronic or written comments on the collection of information by April 18, 2011.

**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:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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, 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, 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. 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.

The GLP regulations contain requirements for the reporting of 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 contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (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.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or government agencies. Failure to include the information in a filing to FDA would mean that Agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports during its inspections of testing laboratories to verify reliability of results submitted in applications.

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 | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 58.35(b)(7) | 300 | 60.25 | 18,075 | 1 | 18,075 |
| 58.185 | 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 | Annual frequency per recordkeeping | Total annual records | Hours per record | Total hours |
|---|---|---|---|---|---|
| 58.29(b) | 300 | 20 | 6,000 | 0.21 | 1,260 |
| 58.35(b)(1)–(b)(6) and (c) | 300 | 270.76 | 81,228 | 3.36 | 272,926 |
| 58.63(b) and (c) | 300 | 60 | 18,000 | 0.09 | 1,620 |
| 58.81(a)–(c) | 300 | 301.8 | 90,540 | 0.14 | 12,676 |
| 58.90(c) and (g) | 300 | 62.7 | 18,810 | 0.13 | 2,445 |
| 58.105(a) and (b) | 300 | 5 | 1,500 | 11.8 | 17,700 |
| 58.107(d) | 300 | 1 | 300 | 4.25 | 1,275 |
| 58.113(a) | 300 | 15.33 | 4,599 | 6.8 | 31,273 |
| 58.120 | 300 | 15.38 | 4,614 | 32.7 | 150,878 |
| 58.195 | 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Governmentwide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–3464 Filed 2–15–11; 8:45 am]

**BILLING CODE 4160–01–P**