FOOD AND DRUG ADMINISTRATION

Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies

OMB Control No. 0910-0119

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations. Specifically, sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA or the 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 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.

Accordingly, we are requesting OMB approval of the information collection provisions associated with FDA's GLP regulations codified at 21 CFR Part 58 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA evaluates recordkeeping associated with nonclinical laboratory studies 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: Respondents to the collection are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies. Respondents are from the private sector (for-profit businesses), as well as state governments and the Federal government.

3. Use of Improved Information Technology and Burden Reduction

The underlying regulations do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate that about ninety-five percent (95%) of respondents will keep some of the required records electronically over the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately half of the 300 respondents, or 150, are small businesses. There are no exemptions to the underlying regulations. However, we believe the reporting and recordkeeping requirements impose minimal burden on respondents while at the same time protect the public health by ensuring the quality and integrity of studies conducted in accordance with the regulations. FDA aids small businesses in complying with its requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with the statutory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection is consistent with 5 CFR §1320.5, excepting a 5-year retention requirement for records relating to toxicology studies supporting investigational new drug

applications (INDs) or applications for investigational device exemptions (IDEs). Because the application process under these regulations is approximately a 5-year process, records must be available to FDA for verification.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), on April 25, 2017 (82 FR 19054), a 60-day notice for public comment was published in the Federal Register. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are made to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidential commercial information is protected from disclosure under section 301(j) of the act. Additionally, to the extent 21 CFR 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes. All records and reports maintained by FDA are kept in secured, limited access areas.

11. Justification for Sensitive Questions

The information collection does not contain questions pertaining to sex, behavior, attitude, religious beliefs, or any matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates 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	Avg. Burden per Recordkeeping	Total Hours
58.29(b); Personnel	300	20	6,000	.21 (13 min.)	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 min.)	1,620
58.81(a)-(c); SOPs	300	301.80	90,540	.14 (8 min.)	12,676
58.90(c) and (g); Animal care	300	62.7	18,810	.13 (8 min.)	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
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.

12b. Annualized Cost Burden Estimate

The annual hourly burden for the information collection requirements in these regulations is estimated at 1,304,157 burden hours. The cost to the respondents is estimated by assuming a cost of $44.91 per hour for 1,304,157 burden hours for a total cost of $58,569,690.87.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	1,304,157	$44.91	$58,569,690.87

[1] May 2016 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The cost of the information collection is absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

The burden has not changed from the currently approved inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to exempt display of the OMB approval date on any documents associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.