UNITED STATES FOOD & DRUG ADMINISTRATION

Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies

OMB Control No. 0910-0119

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection helps to support implementation of 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. Regulations found in 21 CFR part 58, "*Good Laboratory Practice for Nonclinical Laboratory Studies*" (GLP), set forth good laboratory practice requirements for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for food additives, human drugs and biological products, animal drugs, medical devices, and specified products regulated by the Food and Drug Administration (FDA). The applications must include, among other important items, full reports of all studies conducted to demonstrate product safety in man and/or other animals, as well as to ensure adequate quality control for these studies. 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 regulations also require that testing facilities engaged in conducting toxicological studies retain, and make available to regulatory officials, records regarding compliance with GLP regulations. 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.

We therefore request extension of OMB approval for the information collection provisions in 21 CFR part 58 of agency regulations.

2. Purpose and Use of the Information Collection

We use the information to ensure that nonclinical laboratory studies conform to specific quality and integrity standards as established by agency regulations. Respondents to the collection of information are sponsors of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by FDA.

3. Use of Improved Information Technology and Burden Reduction

   The 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, however we anticipate this is usual and customary business practice as submissions to FDA are required electronically unless a waiver to the requirement is granted. Companies We estimate ninety-five percent (95%) of respondents utilize electronic means to satisfy the required recordkeeping.

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

   The information collection poses no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

   The information collection schedule is consistent with statutory and regulatory requirements and includes reporting only on an occasional basis. We believe this imposes minimal burden on respondents while at the same time preserves data quality of information maintained in accordance with the applicable public health regulatory requirements.

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

   Upon review of 5 CFR §1320.5, we note a 5-year retention of records applicable to toxicology studies. This extended retention period is necessary because testing can cover this same 5-year period and entail a process spanning that period. These records must be available to FDA inspectors so they can be examined during on-site visits to verify the quality and integrity of the data throughout the entire course of study.

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

   FDA published a 60-day notice for public comment in the *Federal Register* of July 24, 2020 (85 FR 44900). One comment was received. The commenter suggested that FDA could, "*[e]stablish an automated collection management system through the use of an AI and/or data analytics software. This will increase efficiency and reduce the burden of information collection.*" We appreciate this comment. While we currently have an automated platform in place for the information collection, we continually consider new efficiencies as our limited resources permit.

9. Explanation of Any Payment or Gift to Respondents

   There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII) pertaining to subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII collected is the name of study director, scientists or professionals, and supervisory personnel, which is included in the final study report. The GLP regulations require that, among other things, for each nonclinical laboratory study, a final report be prepared that documents the dates of quality assurance unit inspections, test and control article characterization, , and an overall interpretation of nonclinical laboratory studies. We have minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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.

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Part	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 Part	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	.21 (13 mins.)	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 mins.)	1,620
58.81(a)-(c); SOPs	300	301.80	90,540	.14 (8 mins.)	12,676
58.90(c) and (g); Animal care	300	62.70	18,810	.13 (8 mins.)	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.

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 $51.57 per hour for 1,304,157 burden hours for a total cost of $67,255,376.49.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	1,304,157	$51.57	$67,255,376.49

[1] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/naics4_325400.htm).

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

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

14. Annualized Cost to the Federal Government

Costs to the Federal Government are absorbed through existing resource allocations.

15. Explanation for Program Changes or Adjustments

Upon review of the information collection, we have made no adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

    This information collected will not be published or tabulated.

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

    Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.