**Good Laboratory Practice (GLP) for Non-clinical Laboratory Studies**
**OMB Control No. 0910-0119**
**Supporting Statement**

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

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 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 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 non-clinical 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.

**21 CFR 58.29 (b) - Recordkeeping**
Personnel job descriptions and experience, and training records

**21 CFR 58.35 (b) (7) - Reporting**
Quality assurance unit inspection statement

**21 CFR 58.35 (b) (1), (2) (3), and (c) - Recordkeeping**
Master schedules, protocols, inspection reports, and standard operating procedures

**21 CFR 58.63 (b) and (c) - Recordkeeping**
Equipment inspection, maintenance, calibration, and testing records

**21 CFR 58.81 (a), (b), and (c) - Recordkeeping**
Standard operating procedures

**21 CFR 58.90 (c) and (g)- Recordkeeping**
Documentation of feed and water analysis and animal treatments

**21 CFR 58.105 (a) and (b) - Reporting**
Test and control article characterization

**21 CFR 58.107 (d) - Recordkeeping**
Test article accountability records

**21 CFR 58.113 (a) - Reporting**
Testing of mixtures

**21 CFR 58.120 - Recordkeeping**
Protocols and their amendments

**21 CFR 58.185 - Reporting**
Final report of nonclinical laboratory studies

**21 CFR 58.195 - Recordkeeping**
Documentation, records, and raw data

2. Purpose and Use of the Information Collection

The information is collected as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. 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 on-site audits of records and reports during its inspections of testing laboratories to verify reliability of results submitted in applications. Each year FDA conducts audits and inspections of over 100 studies, at as many laboratories.

3. Use of Improved Information Technology and Burden Reduction

FDA, as an agency, is aware of the dramatic cost improvements possible through computerization and is actively encouraging electronic recordkeeping and electronic submission of new product applications.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection requirements in the GLPs are unique to the testing facility and to each product. There is no duplication. There are no similar data anywhere that could satisfy the purposes set forth in items 1 and 2.

5. Impact on Small Businesses or Other Small Entities

The current regulations do not have an impact on small business that would require a regulatory flexibility analysis.

6. Consequences of Collecting the Information Less Frequently

FDA has no control over the frequency of the information collection. The information is voluntarily submitted by persons wishing to gain approval of research or marketing applications. Each application must contain the required information. Failure to include the information in a filing to FDA would mean that agency scientific experts could not arrive at a valid decision on product safety.

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

The subject information collection requirements are consistent with 5 CFR §1320.5 with the exception of the 5-year retention of records for the toxicology studies. This extended retention period is necessary because it is approximately a 5-year process. 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.

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

FDA has extensive contacts and consults with the affected industry, other government agencies, and international organizations which have an interest in the implementation of the GLP regulations. The regulations have been revised four times since their inception in 1978, to refine and improve their application. These consulting efforts continue.

In accordance with 5 CFR 1320.8(d), on June 12, 2014 (79 FR 33755), a 60-day notice for public comment was published in the Federal Register. One comment was received from the public in response to that notice. Its concerns were outside the scope of the request for comments on the GLP information collection.

9. Explanation of any Payment or Gift to Respondents

There were no payments or gifts made to respondents.

10. Assurance of Confidentiality Provided to Respondents

All records and reports maintained by FDA are kept in limited access areas. The materials are kept confidential in accordance with 18 U.S.C. 1905 as well as section 301 (j) of the Federal Food, Drug, and Cosmetic Act.

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

12a. Annualized Hour Burden Estimate

Table 1--Estimated Annual Reporting Burden[1]

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Avg. Burden 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 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 (in hours) | Total Hours |
|---|---|---|---|---|---|
| 58.29(b) | 300 | 20 | 6,000 | .21 | 1,260 |
| 58.35(b)(1)-(6), (c) | 300 | 270.76 | 81,228 | 3.36 | 272,926[2] |
| 58.63(b), (c) | 300 | 60 | 18,000 | .09 | 1,620 |
| 58.81(a)-(c) | 300 | 301.8 | 90,540 | .14 | 12,676 |
| 58.90(c), (g) | 300 | 62.7 | 18,810 | .13 | 2,445 |
| 58.105(a), (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[2] |

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

[2] FDA discovered that there was an overage in the burden hours for 58.35(b)(1)-(6),(c) in Table 2 above as reported in the 2011 renewal of the information collection due to a mathematical error.

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). In Table 1 the number of respondents times the average number of responses per respondent equals the total annual responses. Total annual responses times average burden per response equals total hours.

For Table 2 the number of record keepers times the average burden per recordkeeper equals the total annual records. Total annual records times average burden per recordkeeping equals total hours.

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 $35.00 per hour for 1,304,157 burden hours for a total cost of $45,645,495.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Industry compliance officer | 1,304,157 | $35.00 | $45,645,495 |

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

There are no additional annual costs to respondents.

14. Annualized Cost to the Federal Government

The additional cost to the Federal Government of this information collection is minimal because manufacturers of human drugs and biological products, animal drugs, medical devices, and food additives must demonstrate the safety and utility of their products by submitting applications to the FDA for research or marketing permits. The information collections arising from these research or marketing permits account for the time and cost burden for evaluation of product safety made by FDA employees.

15. Explanation of Program Changes or Adjustments

There is no change in hourly burden from the previous OMB approval, however upon review we noted a mathematical error and have made a correction which results in 7,000 fewer burden hours. This correction has been noted in Table 2, in response to Question 12a. above.

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. Reasons Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

There are no exceptions to "Certification for Paperwork Reduction Act Submissions" for this collection of information.