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

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Abstract: The Federal Food, Drug, and Cosmetic Act and related statutes require manufacturers of human drugs and biological products, animal drugs, medical devices, and food additives to demonstrate the safety and utility of their product by submitting applications to the 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 promulgated the Good Laboratory Practice (GLP) regulations (21 CFR Part 58) (Attachment A). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures, test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The various acts enforced by FDA require an adequate showing of product safety prior to introduction into the marketplace. The GLPs ensure that the data by which safety is shown have been collected in a valid and accurate manner. Therefore, FDA is requesting the extension of the approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act for the following information collection requirements. This OMB clearance is essential if FDA is to enforce the GLPs and to assure the availability of safe and useful regulated products to American Consumers. Accordingly, we are requesting the approval of the following specific requirements:

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

This information collection does not relate to the American Recovery and Reinvestment Act of 2009.

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. FDA expects submitters to use electronic submission in the near future.

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 §1320.6 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 February 16, 2011, (76 FR 9025) a 60-day notice for public comment was published in the **Federal Register**. No comments were received from the public in response to the information collection.

FDA regularly interacts with trade associations such as the Society of Quality Assurance (SQA) and the Pharmaceutical Manufacturers Association (PhRMA) which represent a broad cross-section of GLP laboratories, and has not received requests to modify the recordkeeping or reporting requirements of the GLP regulations. FDA is also actively involved, internationally, with the Organization for Economic Cooperation and Development (OECD) effort to draft international GLP principals.

At the present time no significant revisions to the GLP regulations have been presented, and no revisions have occurred in the last three years.

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average 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

Table 2: Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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	279,926
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					793,308

The annual burden for the information collection requirements in these regulations is estimated at 1,311,157 burden hours. In Table 1 the number of respondents times the annual frequency of responses equals the total annual responses. Total annual responses times hours per response equals total hours.

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry compliance officer	1,311,157	$35.00	45,890,495

The annual burden for the information collection requirements in these regulations is

estimated at 1,311,157 burden hours.

The cost to the respondents is estimated by assuming a cost of $35.00 per hour for 1,311,157 burden hours for a total cost of $45,890,495.

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

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

An adjustment in the total requested annual hour burden has been made for correcting a previous error in the submission of the data from the last renewal submission request.

The increase of (7000) in the "Due to Adjustment in Agency Estimate" column is a result of correcting a submission error during the last renewal submission request. The currently approved annual burden hour should have been 1,311,157 and not 1,304,157.

The agency, therefore, recalculated the total recordkeeping burden and reporting and made an adjustment (increase of 7000) from the previous total annual burden hours to reflect the correct total requested annual hour burden of 1,311,157.
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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.