U.S. Food and Drug Administration
Electronic Records; Electronic Signatures
OMB Control No. 0910-0303

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations. Specifically, the regulations found at 21 CFR Part 11: *Electronic Records; Electronic Signatures* provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures serving to legally bind subsequent electronic submissions and verify electronic records. Under the regulations, records and reports may be submitted to FDA electronically, with certain provisions. Part 11 establishes conditions for the elective use of electronic records and signatures, including certain procedures and controls to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records, and ensures signatories cannot readily repudiate a signed record as not genuine. The information collection includes the following elements:

- **21 CFR 11.10 – Recordkeeping**; specifies procedures and controls for persons, who use closed systems [controlled access] to create, modify, maintain, or transmit electronic records;

- **21 CFR 11.30 – Recordkeeping**; specifies procedures and controls for persons who use open [no controlled access] systems to create, modify, maintain or transmit electronic records;

- **21 CFR 11.50 – Recordkeeping**; specifies procedures and controls for persons who use electronic signatures;

- **21 CFR 11.100 – Reporting**; requires written certification that persons will regard electronic signatures in their systems as the legally binding equivalent of traditional handwritten signatures; and

- **21 CFR 11.300 –Recordkeeping**; specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

We therefore request OMB approval of the information collection provisions found in 21 CFR Part 11.

2. Purpose and Use of the Information Collection

The underlying regulations apply to all FDA program areas and are intended to permit the widest possible use of electronic technology; compatible with our responsibility to promote and protect the public health. Respondents to the collection are businesses and other for-profit organizations,

state or local governments, Federal agencies, and nonprofit institutions. We believe the regulatory provisions afford respondents great flexibility regarding the use of technology yet still provide a necessary level of confidence in electronic records and electronic signatures. FDA uses the information to facilitate its administrative responsibilities.

3. Use of Improved Information Technology and Burden Reduction

While the regulations do not specifically prescribe what technological methods respondents must employ, specific control measures are discussed. We believe the criteria set forth in the regulations places minimal burden on respondents but simultaneously allows for flexibility as new technological efficiencies are developed.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although the underlying regulations cover all FDA program areas, there are certain recordkeeping requirements to which they may not apply. These are also identified in the regulations.

5. Impact on Small Businesses or Other Small Entities

Though there are no exemptions to the regulations, we believe the requirements favorably impact all respondents. Respondents not confident that their electronic systems meet the minimal requirements of the regulations are free to continue to use traditional signatures and paper documents, consistent with applicable FDA regulations. At the same time, FDA assists small businesses through our Regional Small Business Representatives, through scientific and administrative staffs within the agency, and by providing guidance on our website.

6. Consequences of Collecting the Information Less Frequently

The information collection occurs occasionally and is consistent with the statutory requirements under the Federal Food, Drug, and Cosmetic Act.

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

The recordkeeping requirements deviate from the specifications of 5 CFR 1320.6 in the following respect: persons engaged in drug product manufacturing operations must retain records specifically associated with a drug product for at least 1 year after the expiration date or, in the case of certain OTC drug products dating, 3 years after distribution of the last lot of drug product (see 21 CFR 211.180). Depending on the approved dating period or shelf life of the drug product, it is possible that records would be retained for more than 3 years. Availability of these records provides an opportunity to follow up on complaints and adverse reports received during a drug's marketing period. Failure to have these records available for an investigation could prevent the resolution of undesirable and potentially life-threatening conditions. Audit trails are electronic records that must be kept under 21 CFR §11.10(e) at least as long as the related subject records.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice in the Federal Register of June 19, 2017 (82 FR 27838) soliciting public comment. No comments were received in response to the information collection topics identified in the notice. However, one comment was received regarding substantive aspects of a related FDA draft guidance entitled, "*Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers*," and the comment has been directed to the appropriate agency component for consideration.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality is maintained over trade secret, proprietary, or confidential, commercial or financial information under 21 CFR 20.61 and investigatory records under 21 CFR 20.64. In addition, certain subparagraphs of 21 CFR 314.430 and 514.11 provide confidentiality of information contained in new drug applications (NDA's), abbreviated new drug applications (ANDAs), and new animal drug applications (NADAs). Many of the provisions of Part 11 are designed to preserve confidentiality when using electronic systems.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

*12 a. Annualized Hour Burden Estimate*

The information collection includes provisions found at 21 CFR Part 11.1 which sets forth "*the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper*." The regulations also identify to what records the requirements do not apply. To satisfy the regulatory provisions, respondents must "*employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine*." (21 CFR Part 11.10.) We therefore estimate an initial burden associated with the establishment of standard operating procedures, validation and certification methods, and other quality control measures respondents chose to employ to satisfy these requirements. Our estimate of the recordkeeping burden associated with these provisions is reflected in Table 1 below:

Table 1. --Estimated Annual Recordkeeping Burden[1]

| 21 CFR Part 11; Requirement | No. of Recordkeepers | No. of Records per Recordkeeping | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| 11.10; controls for closed systems | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.30; controls for open systems | 2,500 | 1 | 2,500 | 20 | 50,000 |
| 11.50; signature manifestations | 4,500 | 1 | 4,500 | 20 | 90,000 |
| 11.300; signature/records linkage | 4,500 | 1 | 4,500 | 20 | 90,000 |
| Total | | | | | 280,000 |

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

The regulations also impose a reporting requirement under 21 CFR Part 11.100, which provides for certification of signatures. The "*certification shall be submitted in paper form and signed with a traditional handwritten signature*." We estimate a burden of 1 hour to sign a document containing the identity and handwritten signature of the respondent or respondent's agent consistent with the regulations and submit to FDA for processing. Our estimate of the reporting burden is reflected in Table 2 below:

Table 1. --Estimated Annual Reporting Burden[1]

| 21 CFR Section; Requirement | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Avg. Burden per Response | Total Hours |
|---|---|---|---|---|---|
| 11.100; handwritten certification | 4,500 | 1 | 4,500 | 1 | 4,500 |

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

*12b. Annualized Cost Burden Estimate*

This cost estimate reflects the product of multiplying the total number of respondent burden hours by a cost of $85 – the estimated average cost we attribute to the corresponding activities under the regulations.

| 21 CFR Section | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| 11.100 | 4,500 | $85.00 | $382,500 |
| 11.10 | 50,000 | $85.00 | $4,250,000 |
| 11.30 | 50,000 | $85.00 | $4,250,000 |
| 11.50 | 90,000 | $85.00 | $7,650,000 |
| 11.300 | 90,000 | $85.00 | $7,650,000 |
| TOTAL | | | $24,182,500.00 |

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

Our estimated cost to the Federal government reflects the allocation of 1.5 FTE's who must receive and review submissions under 21 CFR Part 11.100 and ensure that respondents employ recordkeeping measures consistent with the regulations. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/5 employee, we calculate a total cost of $161,112.50 ($107,435 x 1.5).

15. Explanation for Program Changes or Adjustments

A review of the information collection shows no basis for revising the currently approved estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of the information collection required by these regulations.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.