U.S. Food and Drug Administration
Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

OMB Control Number 0910-0510
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) medical device regulation and guidance. Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) amended section 704 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding subsection (g) (21 U.S.C. 374(g)) (http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapVII-partA-sec374.pdf). This amendment authorizes FDA to establish a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. Under the Inspection by Accredited Persons Program, eligible manufacturers may elect to have third parties that have been accredited by FDA (Accredited Persons) conduct some of their inspections instead of FDA. This is a voluntary program.

The guidance document "Guidance for Industry, FDA Staff, and Third Parties – Inspection by Accredited Persons under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007: Accreditation Criteria" describes, among other things, the information an applicant should include in their request for accreditation to demonstrate that they meet the qualifications necessary to become an Accredited Person. (https://www.fda.gov/media/73458/download)

2. Purpose and Use of the Information Collection

Information from this collection will be used by FDA to implement the Inspection by Accredited Persons Program. Specifically, FDA will use the information to determine whether an applicant meets the criteria to become accredited to conduct inspections.

The respondents for this information collection are businesses or other for profit.

3. Use of Improved Information Technology and Burden Reduction

Accredited Persons must have the capability to interface with FDA's electronic data systems, including the FDA Internet websites. At a minimum, this would require a computer system with internet access. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to Accredited Persons and other interested parties. FDA

will accept alternative technology if the technology is compatible with FDA's technology. FDA will accept electronic submissions from any applicant that wishes to submit in this format. FDA estimates that 100% of the respondents will use electronic means to submit the information.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal Agency responsible for the collection of this information. There is no duplication with other data sources.

5. Impact on Small Businesses or Other Small Entities

All of the respondents are businesses. The information being collected has been held to the absolute minimum required for the intended use of the data. Participation in the Inspection by Accredited Persons Program is voluntary. FDA will provide information on its procedures and criteria, through guidance documents and training programs.

6. Consequences of Collecting the Information Less Frequently

Respondents to this information collection respond occasionally, when they are requesting accreditation. Participation in the Inspection by Accredited Persons Program is voluntary. FDA uses the request for accreditation to determine whether applicants meet the criteria to become Accredited Persons. Without collecting the information, FDA would have no means by which to determine whether applicants meet the criteria to become Accredited Persons.

There are no legal obstacles to reduce the burden.

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

There are no special circumstances for this collection of information.

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 for public comment in the Federal Register of March 14, 2019 (84 FR 9352). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII). PII collected is name of the person responsible for compliance with the Quality System regulation. Information from this collection will be used by FDA to implement an Inspection by Accredited Persons program that will train

and accredit persons that wish to conduct inspections of eligible manufacturers of class II and class III medical devices.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

Information submitted by an Accredited Person to obtain approval for participation in the program will be available for disclosure by FDA except to the extent it constitutes trade secret, confidential commercial or personal privacy, or information that is otherwise exempt from public disclosure by law. FDA will post on its Internet site, a list of persons who are accredited (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm).

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, or other matters considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden

Section of the FD&C Act; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
704(g); Request for accreditation	1	1	1	80	80

FDA based these estimates on the number of recent applications. Once an organization is accredited, it will not be required to reapply.

12b. Annualized Cost Burden Estimate

The annualized cost burden estimate includes the salaries for personnel who prepare requests for accreditation. We expect that approximately half of the hour burden will be work performed by a Quality System Specialist* and approximately half by a Regulatory Affairs Professional.**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Quality System Specialist	40	$36	$1,440
Regulatory Affairs Professional	40	$72	$2,880
Total annualized cost burden estimate			$4,320

*The estimated hourly wage rate for a Quality System Specialist, $36, is based on the average annual salary of a Quality System Specialist, $75,583, listed in the American Society for Quality's infographic "Quality Jobs" (downloaded from https://asq.org/career/-/media/90CF12B4221E4FF7BC0165F71C31027E.ashx on 11/12/18). The hourly wage rate assumes a 40-hour work week and is rounded to the nearest dollar.
**The estimated hourly wage rate for a Regulatory Affairs Professional, $72, is based on The Regulatory Affairs Professional Society (RAPS) average total compensation for all U.S.-based regulatory professionals at all levels, $150,422 per year (The Regulatory Affairs Professional Society (RAPS), "2016 Scope of Practice & Compensation Report for the Regulatory Profession," p. 11, downloaded from https://www.raps.org/careers/scope-of-practice-survey on 11/05/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar.

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

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

14. Annualized Cost to the Federal Government

The annualized cost to the federal government will be the cost of two full time FDA employees (FTEs). Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE in CDRH including their non-pay costs*), the estimated annual Federal cost is $540,610.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

The estimated burden for this collection remains unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.