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 the requirements of section 704(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374(g)) and FDA's Inspection by Accredited Persons Program (or AP Program), including requests to become an Accredited Person under the AP Program and a manufacturer's notice of their intention to use an Accredited Person to conduct inspections of their establishment.

Under section 704(g) of the FD&C Act, as amended by section 201 of the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007, FDA established the Inspection by Accredited Persons Program (or AP Program), a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. Under the AP 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.

To assist respondents, FDA developed two guidance documents.[1] 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

[1] As noted on the coversheet for both guidance documents described above, the FDA Reauthorization Act of 2017 (FDARA), signed into law on August 18, 2017, amended several sections of the FD&C Act. The guidance documents were developed and issued prior to the enactment of FDARA, and certain sections may no longer be current as a result. FDA is assessing how to revise the guidance documents to represent our current thinking on this topic.

We note that, while the guidances are intended to assist respondents regarding the AP Program, section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements an Accredited Person must meet. Section 704(g) also provides for a manufacturer's notice of their intention to use an Accredited Person to conduct inspections and provides the other conditions for a device establishment to be eligible for inspection by Accredited Persons. Further, a person who intends to participate in the AP Program can, under section 704(g) of the FD&C Act, request accreditation to conduct inspections or provide notice of their intention to use an Accredited Person to perform inspections.

Therefore, we regard section 704(g) of the FD&C Act to be the primary collection instrument for this information collection.

necessary to become an Accredited Person. The guidance document, "Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007" provides recommendations to respondents on notifying FDA of their intent to request inspection under the AP Program.

We request OMB approval for the information collection provisions of section 704(g) of the FD&C Act and discussed in this supporting statement.

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. FDA will use the information in a request for accreditation to determine whether an applicant meets the criteria to become accredited to conduct inspections (an Accredited Person). The information submitted to FDA in the notification from manufacturers is used to determine whether they satisfy the eligibility criteria for participation in the AP Program.

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

3. Use of Improved Information Technology and Burden Reduction

While requests for accreditation and notifications to FDA do not require a specific format, FDA will accept electronic submissions from any applicant that wishes to submit in an electronic format. We estimate that 100% of the respondents will use electronic means to submit the information.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. FDA is the only Federal Agency responsible for the collection of this information.

5. Impact on Small Businesses or Other Small Entities

The information being collected has been held to the absolute minimum required for the intended use of the data. The information collection does not impose undue burden on small entities. Rather, it is intended to provide specific regulatory options to manufacturers of medical devices. Participation in the Inspection by Accredited Persons Program is voluntary.

FDA aids small business by providing guidance and information through Agency components including the CDRH's Division of Industry and Consumer Education (DICE). DICE provides workshops, onsite evaluations, and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. DICE also maintains a toll-free "800" telephone number and a website that firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

Respondents to this information collection respond occasionally, when they are requesting accreditation or providing notification. Participation in the Inspection by Accredited Persons Program is voluntary. FDA uses the requests for accreditation to determine whether applicants meet the criteria to become Accredited Persons. FDA uses the notification of intent to use an Accredited Person to determine whether manufacturer meets the criteria to participate in the program. Without collecting the information, FDA would have no means by which to determine whether respondents may participate in the program.

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 routinely publishes notices for public comment on the information collection. The burden estimates presented in this supporting statement have been approved by OMB previously (under OMB Control Nos. 0910-0510 and 0910-0569).

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 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 has posted on its Internet site, a list of persons who are accredited.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements an person must meet to be accredited to conduct inspections (an Accredited Person).

The burden estimate for requests for accreditation is based on the number of applications we've received. Once an organization is accredited, it will not be required to reapply.

Under section 510(h) of the FD&C Act (21 U.S.C. 360(h)), domestic manufacturers of class II or class III medical devices are subject to inspection for compliance with the Quality System Regulations (21 CFR Part 820) and other applicable requirements. The AP Program permits eligible manufacturers to use Accredited Persons to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person. A device establishment is eligible for inspection by Accredited Persons if the establishment meets certain conditions of section 704(g)(6) of the FD&C Act, including that they provide notice of their intention to use an Accredited Person to conduct inspections of the establishment.

We estimate there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on informal communications with industry, approximately 10 of these manufacturers may submit a request to use an Accredited Person in any given year.

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden

Activity Under Section 704(g) of the FD&C Act	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Request for accreditation	1	1	1	80	80
Notification of the intent to use an Accredited Person	10	1	10	15	150
Total			11		230

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.**

We expect a notification of intent to use an Accredited Person for an inspection, will be prepared by a Regulatory Affairs Professional.**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Request for accreditation			
Quality System Specialist	40	$36	$1,440
Regulatory Affairs Professional	40	$144	$2,880
Notification of the intent to use an Accredited Person			
Regulatory Affairs Professional	150	$144	$21,600
Total annualized cost burden estimate			$25,920

*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, rounded to the nearest dollar, and doubled to account for benefits and overhead.

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

FDA has requested consolidation of OMB Control Nos. 0910-0510 and 0910-0569. The estimated hour burden has increased by 150 hours as the result of adding the approved burden from OMB Control No. 0910-0569 to this ICR.

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.