Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program
(formerly Requests for Inspection
Under the Inspection by Accredited Persons Program)

0910-0569

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 201 of the Medical Device User Fee and Modernization Act of 2002 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)). 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 this Inspection by Accredited Persons Program (AP Program), eligible manufacturers may elect to have third parties that have been accredited by FDA (accredited person or AP) conduct some of their inspections instead of FDA. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled "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." This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the Accredited Persons (AP) Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

Applicants submit the following information with their notification of intent to use an accredited person to conduct such inspections:

1. Information that demonstrates that the applicant manufactures, prepares, propagates, compounds, or processes class II or class III medical devices;
2. Information that shows that the applicant markets at least one of the devices in the United States;

3. Information that demonstrates that the applicant markets or intends to market at least one of the devices in one or more foreign countries and one or both of the following two conditions are met:
    - One of the foreign countries certifies, accredits, or otherwise recognizes the AP the applicant has selected as a person authorized to conduct inspections of device establishments, or
    - A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection by the FDA or by the AP;
4. Information that shows that the applicant's most recent inspection performed by FDA, or by an AP under this program, was classified by FDA as either "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI)"; and
5. Notification of intent to use an AP, and identification of the AP the applicant selected.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

This program is intended to allow manufacturers greater control over the timing of their inspections. In addition, because some of the FDA accredited persons, are already recognized by other countries as persons authorized to conduct inspections of device establishments, it is possible that in some cases a single AP inspection will meet the requirements of more than one regulatory authority, thereby reducing the need for multiple inspections of the same establishment. Information from these information collection provisions will be used to determine whether a manufacturer is eligible to participate in the AP program. Respondents are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

This program allows alternative appropriate technology. Applications and reports can be electronically submitted if the format is approved by FDA.

Approximately 97% of manufacturer's submit electronic notifications to use an accredited person.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only Federal agency responsible for the inspection of facilities in which medical devices are manufactured in accordance with the Federal Food, Drug, and Cosmetic Act. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Businesses or Other Small Entities

FDA's Center for Devices and Radiological Health (CDRH) has followed the guidelines set by the Small Business Administration (SBD) on what constitutes a small business. For manufacturing, a small business cannot exceed 500 employees. Approximately 95% of U.S. medical device manufacturing establishments are under 500 employees.

Participation in the AP program is voluntary. As such, there is potentially no impact on small businesses unless they elect to participate in the program. FDA aids small business by providing guidance and information through the Division of Industry and Consumer Education (DICE) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. 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 which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

   There is no established frequency for the information collection under the third party review program. Manufacturers may submit requests whenever they wish to use an AP (i.e., occasionally).

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 05/28/2014 (79 FR 30619). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gifts shall be provided to respondents under the regulation.

10. Assurance of Confidentiality Provided to Respondents

    Information regarding APs are available under the Freedom of Information Act and 21 CFR Part 20.

11. Justification for Sensitive Questions

    The information required in a request to use an AP does not include questions that are of a sensitive nature, such as questions regarding sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Activity/ 21 U.S.C. Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Notification regarding use of an accredited person--374(g)	20	1	20	15	300

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may submit a request to use an AP in any given year.

12b. Annualized Cost Burden Estimate

Costs to Respondents:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist	15	$150.00	$2,250.00

For an notification of intent to use an AP for an inspection, the total reporting cost to industry is estimated at $2,250 per submission. Approximately 15 hours are required to complete a notification. The average to industry per hour for this type of work is $150. The estimated submission cost of $2,250 multiplied by 20 submissions per year equals $45,000, which is the aggregated industry reporting cost.

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

Costs to the government are limited to the time required to review the notifications. FDA estimates that one full time equivalent (FTE) position consisting of a combination of scientific and engineering professionals and support staff is required for reviewing and processing the notifications. Based on a cost of $283,487 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $283,487.

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

We adjusted the estimated number of respondents from 100 to 20 based on current information. This adjustment resulted in a 1,200-hour reduction in our burden estimate.

We updated the title of the information collection for clarity and to more accurately describe the information being collected.

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 is not seeking an exemption from display of the effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.