U.S. Food and Drug Administration
Notification of the Intent to Use an Accredited Person
Under the Accredited Persons Inspection Program

OMB Control No. 0910-0569

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA or we) program discussed below and supporting guidance. The Federal Food, Drug, and Cosmetic Act, as amended (the act, FD&C Act) 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 section 510(h) of the act, domestic manufacturers of class II or class III medical devices are subject to inspection for compliance with Quality System regulations (21 CFR Part 820) and other applicable requirements at least once every two years. (See 21 U.S.C. 360(h)). The Inspection by Accredited Persons Program (AP Program) permits eligible manufacturers to schedule qualified independent third-parties to perform certain inspections. This is a voluntary program. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person (AP) under the program.

To participate in the AP program, medical device manufacturers must notify FDA. To assist respondents in this regard, FDA has developed 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*." The guidance provides recommendations and instruction to respondents regarding information needed by FDA to request inspection under the AP program. The guidance document is available on our website at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm085252.pdf.

Specific information collection recommended in the guidance includes the following:

Information that demonstrates that the applicant manufactures, prepares, propagates, compounds, or processes class II or class III medical devices;

Information that shows that the applicant markets at least one of the devices in the United States;

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;

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

Notification of intent to use an AP, and identification of the AP the applicant selected.

We therefore request OMB approval for the information collection provisions found in the referenced guidance and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The AP Program is open to both domestic U.S. device establishments and foreign establishments that are required to register with FDA under section 510(i) of the act, provided such establishments otherwise meet the program's eligibility criteria. Information submitted to FDA under the information collection is used to determine whether respondents satisfy the eligibility criteria.

3. Use of Improved Information Technology and Burden Reduction

While notifications to FDA do not require a specific format, respondents must identify the AP chosen to conduct the inspection. Notifications may be submitted electronically and we estimate 97% of respondents will do so.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While we have issued related guidance entitled, "*Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria*," (approved under OMB Control No. 0910-0510), this information collection is limited to burden associated with notifications to FDA under the AP program.

5. Impact on Small Businesses or Other Small Entities

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. At the same time, FDA aids small business by providing guidance and information through agency components including 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

The information collection is voluntary at the election of respondents.

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 November 21, 2017 (82 FR 55379). 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 provided under this collection is handled in a manner to comply with the FDA regulations implementing the Freedom of Information Act, 21 CFR part 20.

11. Justification for Sensitive Questions

The information collection does not include questions 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

12a. 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)	10	1	10	15	150

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. We therefore estimates 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 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 a 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 10 submissions per year equals $22,500, 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

Government costs include the time required to review the notifications. Assuming that one full time equivalent (FTE) position consisting of a combination of scientific and engineering professional and support staff is allocated to the review and processing of notifications, and using a fully-loaded cost model*, we calculate a cost of $260,286.

FY 2016

FDA Fully Loaded FTE Cost Model (Domestic)	FDA-Wide	CBER	CDER	CDRH	CFSAN	CTP	CVM	NCTR	ORA	OC
1) Pay Costs (By Organization)	**$ 148,633**	**$ 161,146**	**$ 164,508**	**$ 151,057**	**$ 156,004**	**$ 134,817**	**$ 148,834**	**$ 105,220**	**$ 124,657**	**$ 183,470**
2) Non-Pay Costs (By Organization)	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**	**$ 85,759**
Non-Pay Actuals (Included Costs)	$ 59,281	$ 68,420	$ 48,124	$ 30,887	$ 74,353	$ 363,906	$ 19,854	$ 58,810	$ 44,460	$ 33,238
OIMT (Cost Allocation Model excluding personnel)	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726	$ 13,726
General and Administrative Overhead	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752	$ 12,752
3) Rent	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**	**$ 23,470**
GSA Rent (Cost Allocation team analysis)	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190	$ 15,190
OR&RR (Adjusted Cost Allocation team analysis)	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281	$ 8,281
Formulation Fully Loaded Cost = 1+ 2	**$ 234,392**	**$ 246,905**	**$ 250,267**	**$ 236,816**	**$ 241,763**	**$ 220,576**	**$ 234,593**	**$ 190,979**	**$ 210,416**	**$ 269,229**
Total FDA-wide Fully Loaded Cost = 1 + 2 + 3	**$ 257,862**	**$ 270,376**	**$ 273,737**	**$ 260,286**	**$ 265,233**	**$ 244,046**	**$ 258,064**	**$ 214,449**	**$ 233,886**	**$ 292,700**

* FDA Fully Loaded FTE Cost Model (Domestic) for FY 2016. Technical Memorandum, 2016.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments since last OMB approval. We have updated the estimated number of respondents based on the number of notifications received in recent years. We have reduced the number of respondents from 20 to 10 which results in a decrease in annual responses by 10 and a corresponding decrease in annual burden hours by 150.

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.