



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6162]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0569. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

OMB Control Number 0910-0569--Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding paragraph (g) (21 U.S.C. 374(g)). This amendment authorized 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. 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 superseded the Agency’s previous guidance regarding requests for third-party inspection and may be found on the internet at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085252.pdf>. The 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.

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 10 of these manufacturers may use an AP in any given year.

In the *Federal Register* of November 21, 2017 (82 FR 55379), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

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 AP--374(g)	10	1	10	15	150

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the last approval of this information collection, we have updated the estimated number of respondents from 20 to 10 respondents per year, based on the reduced number of notifications received in recent years. This adjustment has resulted in a 150-hour reduction to the total hour burden estimate.

Dated: April 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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