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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier N. Hawkins

[Docket No. FDA-2008-N-0313]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Inspection Under the Inspection by Accredited Persons 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: 202-395-6974, or e-mailed to *baguilar@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: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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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.

Requests for Inspection Under the Inspection by Accredited Persons Program-21 U.S.C. 374(g) (OMB Control Number 0910-0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002, (Public Law 107-250), amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (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. On September 15, 2005, FDA issued a guidance entitled, "Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act 2002," <http://www.fda.gov/cdrh/comp/guidance/1532.html>. This guidance describes the eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an accredited person (AP), conduct a quality system regulation inspection of their establishment under the new inspection by the Accredited Persons Program (AP program), instead of FDA. 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.

In order to meet the eligibility criteria for requesting FDA approval to have an AP conduct a quality system regulations inspection of their establishment instead of FDA, applicants must submit a request with certain information. The following information must be submitted which shows that the applicant:

- (1) “Manufactures, prepares, propagates, compounds, or processes” class II or class III medical devices,
- (2) Markets at least one of the devices in the United States,
- (3) Markets or intends to market at least one of the devices in one or more foreign countries when one or both of the following two conditions are met:
- (a) One of the foreign countries certifies, accredits, or otherwise recognizes the selected AP applicant as a person authorized to conduct inspections of device establishments, or
- (b) A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection conducted by the FDA or an AP.
- (4) Provided the most recent inspection performed by FDA, or by an AP under the AP program and inspection was classified by FDA as either “No Action Indicated” or “Voluntary Action Indicated,” and,
- (5) Provided notice advising FDA of their intent to use an AP, and identifying the AP applicant selected.

In the **Federal Register** of June 3, 2008 (73 FR 31692), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

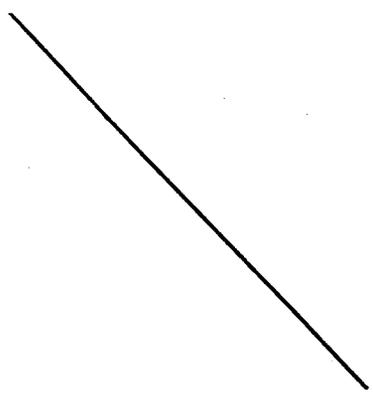
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 U.S.C. Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
374(g)	100	1	100	15	1,500

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

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 100 of these manufacturers may submit a request to use an AP in any given year.



Dated: 8/25/08

August 25, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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Dawn P. Hawkins