provisions. One comment was received but was not related to the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Designation Request	56	1.20	67	60	4,020
Premeeting Packages	47	1.00	47	100	4,700
Total					8,720

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

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11206 Filed 6–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Inspection by an Accredited Person 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 July 7, 2005.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 by an Accredited Person under the Inspection by Accredited Persons Program

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amends section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374) by adding paragraph (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 new Inspection by Accredited Persons Program (AP program), such 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.

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.

The applicant must submit the following information in support of a request for approval to use an AP:

- Information that shows 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 shows 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 as follows:

1. 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

2. 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
- A notice to FDA requesting clearance (approval) to use an AP, and identifying the AP the applicant selected.

In the **Federal Register** of June 3, 2004 (69 FR 31397 at 31398), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment concerning the potential burden associated with the third party inspectional program application process if related cumulative partial inspections over a 2-year period were not recognized by FDA as a single comprehensive inspection. FDA clarified the guidance to state that manufacturers may rely on a single comprehensive inspection or a serious of partial inspections that would cumulatively constitute a complete inspection for the purposes of meeting FDA's biennial inspection requirement. Reapplication to the FDA AP inspection program will not be necessary to conduct each related partial inspection that cumulatively constitutes a single comprehensive inspection of an establishment.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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 for the AP program. Also 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates that there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion in the AP program. Based on informal communications with industry, FDA estimates that approximately 100 of these manufacturers may apply to use an AP in any given year.

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11264 Filed 6–6–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0209]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substances Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Food Contact Substances Notification System.

DATES: Submit written or electronic comments on the collection of information by August 8, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Contact Substances Notification System—21 CFR 170.101 and 170.106—(OMB Control Number 0910–0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of food contact substances except where FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the act is necessary to provide adequate assurance of safety or where FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) require that a food contact notification (FCN) include FDA Form 3480 entitled ''Notification for New Use of a Food Contact Substance'' and that a notification for a food contact substance formulation include FDA Form 3479 entitled ''Notification for a Food Contact Substance Formulation.'' These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.