

submissions, Mammography Matters, and other device-oriented information. The CDRH Internet may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

V. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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, 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.

Title: Requests for Inspection under the Inspection by Accredited Persons Program

Description: 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) 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:

1. Information that shows 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 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:

a. 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

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

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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 27, 2004.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. 04–12683 Filed 6–1–04; 11:45 am]
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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker License

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs

Regulations (19 CFR 111.51), the following Customs broker license are canceled without prejudice.

Name	License #	Issuing port
Paul T. Kimoto	04831	Honolulu.
Air Express International Agency, Inc	3024 & 03016	New York.
Columbia Shipping Inc.	12259	San Francisco.
Dateline Forwarding Services Inc.	13276	Atlanta.
Jacky Maeder, Ltd.	10446	San Francisco.
Celadon-Jacky Maeder Co.,	14412	San Francisco.

Dated: May 26, 2004.

Jayson P. Ahern,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 04-12534 Filed 6-2-04; 8:45 am]

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DEPARTMENT OF HOME LAND SECURITY

Bureau of Immigration and Customs Enforcement

Agency Information Collection Activities: Comment Request

ACTION: Request OMB approval; exemption from NSEERS registration requirements (File No. OMB-40).

The Department of Homeland Security, Immigration and Customs Enforcement (ICE) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on November 28, 2003 at 68 FR 66846, allowing for a 60-day public comment period. No comments were received by the ICE on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 6, 2004. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice should be directed to the Office of Management and Budget, Attn: Desk Officer for Homeland Security, Office of Management and Budget Room 10235, Washington, DC 20503; telephone 202-395-7316. The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Exemption from NSEERS Registration Requirements.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number. File No. OMB-40. U.S., Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and Households. This information collection allows an alien to seek an exemption from the NSEERS registration requirements by submitting a letter to the Department of Homeland Security containing specific information.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5,800 responses at 30 minutes (.5 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,900 annual burden hours.

If additional information is required contact: Mr. Richard A. Sloan, Director, Regulations and Forms Services, Citizenship and Immigration Services, Department of Homeland Security, Room 4034, 425 I Street, NW., Washington, DC 20536.

Dated: May 28, 2004.

Stephen Tarragon,

Senior Management Analyst.

[FR Doc. 04-12545 Filed 6-2-04; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4903-N-37]

Notice of Submission of Proposed Information Collection to OMB; PHA Development Cost Budget, Cost Statement, Actual Development Cost Certificate

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

HUD is requesting extension of OMB approval to collect information from Public Housing Agencies (PHAs) c Public Housing Agencies (PHAS) documenting budgets and costs for the development of low-income housing and for the costs of acquisition and relocation.

DATES: *Comments Due Date:* July 6, 2004.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577-0036) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a