

plans to release a second version of the formats in six to nine months, or perhaps sooner, depending on the nature of initial feedback. Once the formats are stabilized, AHRQ plans to release new versions annually. The Agency will follow the same process for formats developed for other settings.

AHRQ realizes that using Version 0.1 Beta paper forms is not the optimal way to collect patient safety data. Over time, computer software (developed in the private sector) will make use of the formats much more efficient. However, because the Agency plans an early second release of the Common Formats, it cautions software developers to understand that the first release of the formats will likely be substantially enhanced.

More information on the feedback process can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/index.html>.

Dated: August 21, 2008.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. E8-19910 Filed 8-28-08; 8:45 am]

BILLING CODE 4160-90-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-65]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organizations Sanction Regulations—42 CFR 1004.4, 1004.50, 1004.60, and 1004.70; *Use:* The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. *Form Number:* CMS-R-65 (OMB# 0938-0444); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 53; *Total Annual Hours:* 14,310.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *October 28, 2008*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development,

Attention: Document Identifier/OMB Control Number \_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 22, 2008.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. E8-19975 Filed 8-28-08; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[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 September 29, 2008.

**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](mailto: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.

**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 BURDEN<sup>1</sup>

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

<sup>1</sup> 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: August 25, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-20113 Filed 8-28-08; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special

Emphasis Panel; Category A and B Pathogens.

*Date:* September 18, 2008.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

*Contact Person:* Lucy A. Ward, DVM, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-594-6635, [lward@niaid.nih.gov](mailto:lward@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 21, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-19916 Filed 8-28-08; 8:45 am]

BILLING CODE 4140-01-M