Dated: February 8, 2007.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E7–2503 Filed 2–13–07; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH) announces the following meeting of the aforementioned committee.

*Times and Dates:* March 14, 2007, 8:30 a.m.–5 p.m. March 15, 2007, 8:30 a.m.–12:30 p.m.

*Place:* Crowne Plaza Hotel, Atlanta-Buckhead, 3377 Peachtree Road, NE., Atlanta, GA 30326, telephone 404 233–7061.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

*Purpose:* The Committee provides advice and guidance to the Secretary, Health and Human Services; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The committee also reviews and reports regularly on childhood lead poisoning prevention practices and recommends improvements in national childhood lead poisoning prevention efforts.

*Matters to be Discussed:* Update on Lead and pregnancy Workgroup activities, discussions of laboratory capacity to analyze BLL< 2 µg/dL, and actions needed to meet the 2010 elimination goal. Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

*For Further Information Contact:* Claudine Johnson, Clerk (Contractor), Lead Poisoning Prevention Branch, Division of Environmental Emergency Health Services, NCEH, CDC, 4770 Buford Hwy, NE., Mailstop F–40, Atlanta, GA 30341, telephone 770 488–3629,fax 770 488–3635.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 8, 2007.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E7–2515 Filed 2–13–07; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006N–0452]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

**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 March 16, 2007.

**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.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**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:

**Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension**

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment; a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment, (2) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices.

In the **Federal Register** of November 15, 2006 (71 FR 66543), FDA published a 60-day notice soliciting comments on the proposed collection of information. In response to that notice, no comments were received.

The respondents to this collection of information are device manufacturers and contact sterilizers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 801.150(e) | 90 | 20 | 1,800 | 4 | 7,200 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 801.150(a)(2) | 90 | 20 | 1,800 | 0.5 | 900 |

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

FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements per year. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which are required under the reporting section of this collection.

Dated: February 7, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–2467 Filed 2–13–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0041]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Procedures for the Clinical Laboratory Improvement Amendments of 1998 Categorization

**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 for an existing collection of information and to allow 60 days for public commein response to the notice. This notice solicits comments on administrative procedures for the Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization.

**DATES:** Submit written or electronic comments on the collection of information by April 16, 2007.

**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:** Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1472.

**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 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.

**Administrative Procedures for CLIA Categorization (42 CFR 493.17)**

A draft guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released for comment on August 14, 2000. The document describes procedures FDA will use to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer since the labeling (including operating instructions) is included in the 510(k) or PMA. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The draft guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

A previous 60-day notice that published August 14, 2000 (65 FR 49582) announced the availability of a draft guidance and did not include a Paperwork Analysis Section. This 60-day notice for public comment supersedes that notice and is correcting that error.

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