

Dated: February 8, 2007.

Joan F. Karr,

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

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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.

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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 BURDEN¹

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.