

employees will not be considered for membership. Members may be invited to serve up to four-year terms. Consideration is given to representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, and a current curriculum vitae. E-mail addresses are requested if available.

Nominations should be sent in writing and postmarked by September 1, 2003, to: Demetria Gardner, National Immunization Program, CDC, 1600 Clifton Road, NE., Mailstop E-61, Atlanta, Georgia 30333. Telephone and facsimile submissions cannot be accepted.

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: August 5, 2003.

Alvin Hall,

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

[FR Doc. 03-20483 Filed 8-11-03; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control

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) announces the following subcommittee and committee meetings.

The Science and Program Review Subcommittee (SPRS) and the Advisory Committee for Injury Prevention and Control (ACIPC) will meet to evaluate and discuss applications for Program Announcement Numbers 03077, Community-Based Interventions to Reduce Motor Vehicle-Related Injuries; 03100, Research to Improve Smoke Alarm Maintenance and Function; 03106, Development and Validation of Measures to Assess Outcomes of Mild Traumatic Brain Injury; and Small Business Innovation Research applications reviewed by the National Institutes of Health.

Name: Science and Program Review Subcommittee to ACIPC.

Time and Dates: 2 p.m.–3:10 p.m., August 18, 2003.

Place: Koger, Yale Building, Room 2054, 2495 Flowers Road, Atlanta, Georgia 30341.

Status: Open: 2 p.m.–2:10 p.m., August 18, 2003. Closed: 2:20 p.m.–3:10 p.m., August 18, 2003.

Purpose: The Subcommittee provides advice on the needs, structure, progress, and performance of the National Center for Injury Prevention and Control (NCIPC) programs. The Subcommittee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Subcommittee also advises on priorities for research to be supported by contracts, grants, and cooperative agreements and provides concept review of program proposals and announcements.

Matters To Be Discussed: Agenda items for the open portion of the oversight include information about upcoming meetings. Beginning at 2:20 p.m., August 18, 2003, through 3:10 p.m., the Subcommittee will conduct the secondary review in closed session. The secondary review will include discussion and evaluation of results of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel's deliberations of applications in response to Program Announcements #03077, Community-Based Interventions to Reduce Motor Vehicle-Related Injuries; #03100, Research to Improve Smoke Alarm Maintenance and Function; and #03106, Development and Validation of Measures to Assess Outcomes of Mild Traumatic Brain Injury. The secondary review will also include discussion and evaluation of Small Business Innovation Research applications reviewed by the National Institutes of Health. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Name: Advisory Committee for Injury Prevention and Control.

Time and Dates: 3:15 p.m.–4 p.m., August 18, 2003.

Place: Koger/Yale Building, Room 2054, 2495 Flowers Road, Atlanta, Georgia 30341.

Status: Open: 3:15 p.m.–3:35 p.m., August 18, 2003. Closed: 3:35 p.m.–4:00 p.m., August 18, 2003.

Purpose: The committee advises and makes recommendations to the Secretary, Health and Human Services, the Director, CDC, and the Director, NCIPC, regarding feasible goals for the prevention and control of injury. The committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The committee provides advice on the appropriate balance of intramural and extramural research, and also provides guidance on the needs, structure, progress and performance of intramural programs, and on extramural scientific

program matters. The committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The committee also recommends areas of research to be supported by contracts and cooperative agreements and provides concept review of program proposals and announcements.

Matters To Be Discussed: Agenda items for the open portion includes an update on Center activities. Beginning at 3:35 p.m., August 18, 2003, through 4 p.m., during the closed portion, the committee will vote on results of the secondary review. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Ms. Louise Galaska, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341-3724, telephone 770/488-4694.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of the meeting.

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: August 5, 2003.

Alvin Hall,

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

[FR Doc. 03-20482 Filed 8-11-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0194]

Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below has been submitted to the Office of Management

and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by September 11, 2003.

ADDRESSES: 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 written 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.

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

In the **Federal Register** of May 21, 2003 (68 FR 27819), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the reporting 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

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.150(a)(2)	90	20	1,800	.5	900

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

FDA's estimate for the reporting burden is based on actual data obtained from industry during the past 3 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 each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part time basis for only one customer while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or is an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this

regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours (90 firms x 20 agreements x 4 hours).

The recordkeeping requirements for respondents consists of making copies and maintaining the actual reporting requests which were required under reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours.

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-20523 Filed 8-11-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2003N-0344]

Consumer-Directed Promotion; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on consumer-directed promotion of prescription drugs. The purpose of the meeting is to enable the agency and other persons and organizations to present the results of their research on consumer-directed promotion of prescription drug products through print, broadcast, and other types of media. FDA is particularly