

The following individuals have been designated to serve on the Commission's Performance review Board:

Rosemarie A. Straight, Executive Director, Chair.

Howard J. Beales, Director, Bureau of Consumer Protection.

William E. Kovacic, General Counsel.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-73-03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project: The Second Injury Control and Risk Survey (ICARIS 2) Phase 2—New—The National Center for

Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC). This project will use data from a telephone survey to measure injury-related risk factors and guide injury prevention and control priorities including those identified as priorities in *Healthy People 2010* objectives for the nation. Injuries are a major cause of premature death and disability with associated economic costs of over 150 billion dollars in lifetime costs for persons injured each year. *Healthy People 2010* objectives and the recent report from the Institute of Medicine, *Reducing the Burden of Injury*, call for reducing this toll.

In addition to national efforts, NCIPC funds injury control prevention programs at the state and local levels. These programs need data both to establish their prevention priorities and monitor their performance. The use of outcome data (e.g., fatal injuries) for measuring program effectiveness is problematic because cause-specific events are relatively rare and because data on critical risk factors (e.g., was a helmet worn in a bike crash or was a smoke detector present at a fatal fire?) are often missing. Because these risk factors are early in the causal chain of injury, they are what injury control programs target to prevent injuries. Accordingly, monitoring the level of injury risk factors in a population can help programs set priorities and evaluate interventions.

The first Injury Control and Risk Factor Survey (ICARIS), conducted in 1994, was a random digit dial telephone survey that collected injury risk factor and demographic data on 5,238 English- and Spanish-speaking adults (greater than or equal to 18 years old) in the

United States. Proxy data were collected on 3,541 children <15 years old. More than a dozen peer-reviewed scientific reports have been published from the ICARIS data on subjects including dog bites, bicycle helmet use, residential smoke detector usage and fire escape practices, attitudes toward violence, suicidal ideation and behavior, and compliance with pediatric injury prevention counseling.

ICARIS-2, a national telephone survey about injury, which began in the summer of 2000, has collected data on more than 8,700 of the targeted 10,200 respondents to date. The first phase of the survey was initiated as a means for monitoring the injury risk factor status of the nation at the start of the millennium. The second phase of the survey is needed to expand knowledge in areas investigators could not fully explore, previously. By using data collected in ICARIS as a baseline, data collected in ICARIS-2 Phase-2 will be used along with data currently being collected (ICARIS-2 Phase-1) to measure changes and gauge the impact of injury prevention policies. The ICARIS-2 surveys may also serve as the only readily available source of data to measure several of the *Healthy People 2010* injury prevention objectives. In order to more fully monitor injury risk factors and selected year *Healthy People 2010* injury objectives, as well as evaluate the effectiveness of injury prevention programs, the second phase (ICARIS-2 Phase-2) of the current national telephone survey on injury risk is being implemented. The only cost to the respondents is the time involved to complete the survey. The estimated annualized burden is 1521.

| Form/Respondent category | Number of respondents | Frequency of response | Average burden per Response (in hours) |
|--|-----------------------|-----------------------|--|
| Screening: | | | |
| Ineligible Households plus Nonhouseholds | 2800 | 1 | 1/60 |
| Unable to reach respondent, 8 attempts | 1000 | 4 | 6/60 |
| Refusals—Screener | 3150 | 1 | .5/60 |
| CATI Survey Instrument: | | | |
| Refusals—CATI | 900 | 1 | 1.5/60 |
| Partial Interview | 150 | 1 | 10/60 |
| Completed Interviews | 4000 | 1 | 15/60 |

Dated: October 17, 2003.

Gaylon D. Morris,

*Acting Director, Executive Secretariat,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Notice of Meeting

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 committee meeting.

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., November 13, 2003.

8 a.m.–5 p.m., November 14, 2003.

Place: Hilton Hotel, 333 O'Farrell Street, San Francisco, California 94102, telephone 415/771-1400, fax 415/202-7033.

Status: Open 8 a.m.–8:30 a.m., November 13, 2003.

Closed 8:30 a.m.–5 p.m., November 13, 2003.

Closed 8 a.m.–5 p.m., November 14, 2003.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas. It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene in open session from 8–8:30 a.m. on November 13, 2003, to address matters related to the conduct of Study Section business. The remainder of the meeting will

proceed in closed session. The purpose of the closed sessions is for the Study Section to consider safety and occupational health-related grant applications. These portions 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, Centers for Disease Control and Prevention, pursuant to Public Law 92-463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Price Connor, Ph.D., NIOSH Health Scientist, 1600 Clifton Road, NE, Mailstop E-20, Atlanta, Georgia 30333, telephone 404/498-2511, fax 404/498-2569.

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: October 21, 2003.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0057]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Final Guidance for Industry: How to Use E-Mail to Submit a Protocol

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: Fax written comments on the collection of information by November 26, 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, or e-mail: *Fumie_Yokota@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B-41, 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:

How to Use E-Mail to Submit a Protocol

The Center for Veterinary Medicine (CVM) may review protocols for safety and effectiveness studies of new animal drugs submitted by sponsors. The review of protocols facilitates the drug review and approval processes.

Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for effectiveness studies are required under 21 CFR 514.117(b). The burden hours associated with preparing the protocols and appendices were reported and approved under OMB control number 0910-0119 for nonclinical laboratory studies and OMB control number 0910-0346 for adequate and well-controlled effectiveness studies. In this guidance document, CVM is giving sponsors the option to submit a protocol as an attachment via the Internet.

In the **Federal Register** of April 4, 2003 (68 FR 16522), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Form FDA No. | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 3,536 | 190 | 0.52 | 100 | 0.20 | 20 |

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