

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).

[FR Doc. 03-26983 Filed 10-24-03; 8:45 am]

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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.