Management Specialist, CDC, 1600 Clifton Road, NE, M/S D50, Atlanta, Georgia 30333, telephone 404/639–7250.

Dated: September 24, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97–25834 Filed 9–29–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section; NIOSH 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, National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.-5:30 p.m., October 29–30, 1997.

Place: National Institute for Occupational Safety and Health, 1095 Willowdale Road, Morgantown, West Virginia, 26505–2888.

Status: Open business session, 8 a.m.-8:30 a.m., October 29, 1997; Closed evaluation sessions 8:30 a.m.-5:30 p.m., October 29, 1997; and 8 a.m.-5:30 p.m., October 30, 1997.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) 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 which 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 a.m.-8:30 a.m. on October 29, 1997, to address matters related to the conduct of Study Section business. The meeting will proceed in closed session from 8:30 a.m. until scheduled adjournment (5:30 p.m.) on October 29, 1997. The meeting will continue in closed session from 8 a.m. until scheduled adjournment (5:30 p.m.) or earlier on October 30, 1997. The purpose of the closed sessions is for the Safety and Occupational Health 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 552(c) (4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, telephone 304/285–5979.

Dated: September 18, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–25948 Filed 9–29–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0385]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 (the PRA).

DATES: Submit written comments on the collection of information by October 30, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Premarket Approval of Medical Devices—Part 814 (OMB Control Number 0910–0231—Reinstatement)

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth requirements for premarket approval of certain medical devices. Under section 515 of the act, an application must contain several pieces of information, including: Full reports of all information concerning investigations showing whether the device is safe and effective; a statement of components; a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device; and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a premarket approval application (PMA) for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMA's for class III (premarket approval) medical devices, in order to facilitate the approval of PMA's for devices that have been shown to be safe and effective and otherwise meet the statutory criteria for approval and to ensure the disapproval of PMA's for devices that have not been shown to be safe and effective and that do not otherwise meet the statutory criteria for approval.

Under § 814.15, an applicant may submit in support of a PMA studies from research conducted outside the United States, but an applicant must explain in detail any differences between standards used in a study to support the PMA's and those standards found in the Declaration of Helsinki. Section 814.20 provides a list of information required in the PMA, including: A summary of information in the application, a complete description of the device, technical and scientific information, and copies of proposed labeling. Section 814.37 provides requirements for an applicant who seeks to amend a pending PMA. Under § 814.39, an applicant must submit a supplement to the PMA before making a change affecting the safety or effectiveness of the device. Section 814.82 sets forth postapproval requirements FDA may propose, including periodic reporting on safety, effectiveness, reliability, and display in the labeling and advertising of certain warnings. Section 814.82 requires the maintenance of records to trace patients and the organizing and indexing of records into identifiable files to enable