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

FDA to determine whether there is reasonable assurance of the device's continued safety and effectiveness. Section 814.84 specifies the contents of periodic reports. The applicant determines what records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation part 820 (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required to be maintained as conditions of approval to ensure the device's continuing safety and effectiveness.

Respondents to this information collection are persons filing an application for approval of a Class III medical device. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.15, 814.20, and 814.37	52	1	52	837.28	43,539
814.39	493	1	493	73.15	36,063
814.82	545	1	545	9.14	4,983
814.84	545	1	545	18.29	9,966
Total					94,551

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

In March 1997, while completing work on the CDRH Annual Information Collection Budget, an error was discovered on this information collection's burden hours by CDRH program staff. This error was not discovered until after the publishing of this information collection's 60-day notice in the **Federal Register** of January 7, 1997 (62 FR 995), Docket No. 96N–0491. The narrative portion of the **Federal Register** notice correctly stated that 52 original PMA's and 493 PMA Supplements were processed each year. The burden chart, however, incorrectly stated that 545 original PMA's and 545 PMA Supplements were processed each year (the 545 figure was derived by adding the 52 original and 493 PMA supplements together). When the correct number of respondents was plugged into the burden hour table and the numbers recalculated, the new total burden hours equals 104,020 hours, a savings of 416,583 hours from the original 1997 figure of 520,603.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.82 (a) (5) and (a) (6)	567	1	567	16.7	9,469
Total					9,469

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

FDA estimates that the cost to device manufacturers to comply with the requirements for premarket approval of medical devices is approximately $34.95 million per year. The industry-wide cost estimate for PMA's is based on an average fiscal year annual rate of receipt of 52 PMA original applications and 493 PMA supplements, using fiscal years 1991 through 1995 data.

The cost data for PMA's is based on data provided by manufacturers in 1985 by device type and cost element. The specific cost elements for which FDA has data are as follows:

(1) Clinical investigations: 67 percent of total cost estimate,

(2) Submitting additional data or information to FDA during a PMA review: 12 percent,

(3) Additional device development cost (e.g., testing): 10 percent and,

(4) PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11 percent.

A weighted average calculation in 1985 produced a total cost of $280,000 for a PMA application. These cost estimates are considered to be solely attributable to PMA requirements. FDA does not have more recent data on the cost to manufacturers of collecting, analyzing, and preparing the data needed for a PMA submission. FDA has adjusted the 1985 estimate for inflation (using an average of 7.5 percent per year for the health care sector) and multiplied it by 52 (the average number of PMA's submitted annually) to yield an annual cost attributable to PMA's of $32,323,200 ($280,000 x index of 2.22 x 52).

FDA estimates that 493 PMA supplements will be submitted annually. No recent information on the cost of PMA supplements has been collected from medical device manufacturers. However, the agency has taken an earlier cost estimate for PMA supplements ($2,400 per supplement) and adjusted it for inflation. The annual cost of PMA supplements is estimated to be $2,626,704 (493 x $2,400 x 2.22 index factor).

Thus, the cost estimate for PMA's and PMA supplements is $34,949,904. This figure represents the burden on industry due to the PMA approval requirement. This cost includes both the effect of the statutory requirement and the effect of the agency's implementation of the statute.

The recordkeeping burden in this section requires the maintenance of

records to trace patients, and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These requirements are to be performed only by those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMA's are eventually approved and 75 percent of those have original clinical trial data. Therefore, about 27 PMA's a year would be subject to these requirements. Also, because the requirements apply to all active PMA's, all holders of active PMA applications must maintain these records. PMA's have been required since 1976, so there are around 567 active PMA's that could be subject to these requirements (21 years x 27 per year). Each study has about approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 16.7 hours. The aggregate burden for all 567 holders of approved original PMA's, therefore, is 9,469 hours (567 approved PMA's with clinical data x 16.7 hours per PMA).

The applicant determines what records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the Current Good Manufacturing Practices for medical devices regulation part 820 may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

With the additional 9,469 hours or recordkeeping, the total annual burden is 104,020 hours.

Dated: September 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25938 Filed 9-29-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part D, Chapter DE, Office of External Affairs (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November, 9, 1995, and in pertinent part at 56 FR 29484, June 27, 1991) is amended to reflect the title change of the Industry and Small Business Liaison Staff. The title is being changed to more accurately reflect the expanding concerns and community issues in the jurisdictions containing various FDA headquarter facilities. The Industry and Small Business Liaison Staff will be retitled as the Industry, Small Business and Community Affairs Staff. The current functions remain the same with the addition of two new functions.

Delete the **Industry and Small Business Liaison Staff** (DE–1) in its entirety and insert the following:

Industry, Small Business and Community Affairs Staff (DE–1). Advises and assists the Commissioner and other Agency officials on industry-related issues which have an impact on policy, directions, and goals.

Serves as the Agency focal point for overall industry liaison and communication activities within FDA, including FDA Centers, and between FDA and FDA-regulated industry, industry trade associations, and scientific associations.

Serves as liaison with other Agency components to provide advice and assistance to small manufacturers and scientific associations to promote their understandings of and compliance with FDA regulations.

Develops and maintains effective channels of communication with regulated industry, professional societies, and trade and scientific associations.

Serves as liaison with local civic organizations in jurisdictions containing or contiguous to the various FDA headquarters facilities.

Provides official contact point within the Agency for discussion and resolution of community issues and concerns arising in connection with the construction, renovation, or ongoing operation of FDA's widely dispersed physical point.

Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: September 2, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–25782 Filed 9–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–211]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* State Child Health Plan and Supporting Information Collection Requirements Referenced in Title XXI of the Social Security Act; *Form No.:* HCFA–R–211, OMB # 0938–0707; *Use:* This Model template will enable states to apply for funds under Title XXI of the Social Security Act, to initiate and expand the provision of child health insurance to uninsured, low income children in a effective and efficient manner that is coordinated with other sources of health coverage for children; *Affected Public:* State, Local or Tribal Government; Number of Respondents: 56; *Total Annual Responses:* 56; *Total Annual Hours:* 8,960.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: