U.S. commercial airlines and are potentially exposed to ionizing radiation and disruption of circardin rhythms, two exposures that may adversely affect reproductive function. Teachers will be enrolled as an external comparison group for this study.

Data from company personnel records containing demographic and work history information will be used to estimate workplace exposures. Each women will be asked to complete a telephone questionnaire on reproductive history and other factors (such as cigarette smoking) that may influence reproductive function. Each questionnaire will take approximately 60 minutes to complete. Medical records will be requested to confirm adverse reproductive outcomes reported by the participants. The risk of adverse reproductive outcomes between the two groups of women will then be compared.

The total cost to respondents to estimated at $102,000.

Respondents	Number of respondents	Number of responses respondent	Avg. burden per response	Total burden
Workers	6,200	1	1.0	6,200
Medical providers	1,200	1	0.5	600
Total				6,800

Dated: September 13, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–24230 Filed 9–16–99; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0407]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Reclassification Petitions for Medical Devices.

DATES: Submit written comments on the collection of information by November 16, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reclassification Petitions for Medical Devices; 21 CFR 860.123 (OMB Control Number 0910–0138—Extension)

FDA has the responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a medical device from any one of three classes (I, II, and III) to another class. The reclassification procedures (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.133	11	1	11	500	5,500

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

Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements and have reviewed the documentation submitted.

Dated: September 13, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–24237 Filed 9–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2874]

Development of Guidance Documents for Medical Devices Regulated by the Center for Biologics Evaluation and Research; Stakeholders Input Under FDA Modernization Act of 1997; Public Meeting and Teleconference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and teleconference entitled ''Development of Guidance Documents for Medical Devices Regulated by the Center for Biologics Evaluation and Research-Stakeholders Input Under FDA Modernization Act of 1997.'' The goals of the public meeting and teleconference are to explain to stakeholders the process and development of medical device guidance documents under good guidance practices (GGP's) and how to participate in both processes and to give stakeholders the opportunity to provide input on what they think the Center for Biologics Evaluation and Research's (CBER's) priorities should be regarding medical devices regulated by CBER. The agency is also requesting comments prior to the meeting, from stakeholders on proposals of priorities for development of guidance documents related to CBER-regulated medical devices.

DATES: The meeting will be held on November 15, 1999, 1 p.m. to 4 p.m. (Eastern Time). The teleconference will be held on the same day. See Table 1 in section III of this document for the scheduled times and locations of the teleconference. The deadline for registration for the meeting or teleconference is November 8, 1999. Comments are requested before the meeting by October 1, 1999, or after the meeting by December 15, 1999.

ADDRESSES: The meeting will be held at the Masur Auditorium, National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Bethesda, MD. See Table 1 in section III of this document for the scheduled locations of the teleconference. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melanie N. Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3841, FAX 301–827–3079, or e-mail ''Whelan@CBER.FDA.GOV''.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 406(b) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (21 U.S.C. 393(f) and (g)), CBER held a series of public meetings to discuss its statutory obligations under FDAMA for biologics. The meetings were held in Washington, DC, on August 14, 1998 (63 FR 39877, July 24, 1998); in Oakland, CA, on August 28, 1998; in Bethesda, MD, on December 1, 1998 (63 FR 58743, November 2, 1998); and in San Francisco, CA, and Boston, MA, on April 28, 1999 (64 FR 13804, March 22, 1999). The FDA Pacific Regional Office sponsored a grassroots meeting on September 15, 1998 (63 FR 42052, August 6, 1998), in Irvine, CA, with the biotechnology industry.

At some of the earlier public meetings, a recurring theme was dissatisfaction with the handling of medical devices regulated by CBER. Important concerns were related to CBER procedures and standards for medical device products similar to products regulated by the Center for Devices and Radiological Health (CDRH). In response to these concerns, CBER developed the Device Action Plan in order to facilitate the implementation of the device provisions of FDAMA and to ensure consistency of policy and procedures between CBER and CDRH. CBER announced the completed Device Action Plan at the CBER Stakeholders Meetings held in San Francisco, CA, and Boston, MA, on April 28, 1999 (64 FR 13804, March 22, 1999). The following issues have been outlined in the Device Action Plan: (1) Compliance and team biologics issues (application of certain good manufacturing practices (GMP's) and compliance policy), (2) enhancing communication with industry and within FDA, (3) coordination with CDRH, and (4) improvement of device review performance. The Device Action Plan has been posted on the CBER web site at ''http://www.fda.gov/cber/dap/dap.htm''.

The public meeting and teleconference will be gathering information on all medical devices including those regulated under the Federal Food, Drug, and Cosmetic Act and those licensed under the Public Health Service Act. The public meeting and teleconference announced in this notice is intended to: (1) Explain to stakeholders the process and development of medical device guidance documents under GGP's and how they can participate in both processes, and (2) give stakeholders the opportunity to provide input on what they think CBER's priorities should be regarding the development of guidance documents related to medical devices regulated by CBER.

In preparation for the November 15, 1999, public meeting, FDA is soliciting comments from stakeholders on proposals of priorities for development