Building and Fire Research Laboratory, Gaithersburg, MD 20899–0001.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: To provide peer review of the draft research protocol of a study of burn hazards associated with full ensemble fire fighters' protective clothing and equipment. Also, to exchange information among government, Page 2 stakeholders, and interested parties on the scientific, procedural, and related aspects of the study.

Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study protocol, ''Full Ensemble Fire Testing of Fire Fighters' Protective Clothing and Equipment.''

Matters to be Discussed: The agenda will include a review of the NIST research plan; request for field experience and other information and scientific input on the planned research topics; and scientific discussion on the types and usage of thermal sensors of relevance to exposure estimation. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments will also be considered.

Contact Person for Additional Information: Thomas K. Hodous, M.D., Project Officer, Division of Safety Research, NIOSH, CDC, M/S P–1172, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888. Telephone 304/285–5943, E-mail thh1@cdc.gov. Copies of the draft protocol may be obtained by contacting Dr. Hodous.

Dated: October 23, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–29098 Filed 10–29–98; 8:45 am]

BILLING CODE 4160–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0331]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; FDAMA Third-Party Review

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 (PRA).

DATES: Submit written comments on the collection of information by November 30, 1998.

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. Schlosburg, 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.

Medical Devices; FDAMA Third-Party Review (OMB Control Number 0910–0375—Extension)

Section 210 of FDAMA establishes a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the Third-Party Review Pilot Program previously conducted by FDA, participation in this Third-Party Review Pilot Program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers will have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to implement the Accredited Person Review Program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Description of Respondents: Businesses or other for profit organizations.

In the **Federal Register** of August 4, 1998 (63 FR 41575), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Respondent	Total Hours
Requests for accreditation	40	1	40	24	960
510(k) reviews conducted by accredited third parties	35	4	140	40	5,600
Total hours					6,560

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	35	4	140	10	1,400[2]

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Due to clerical error, the recordkeeping burden hours for 510(k) reviews that appeared in a notice issued in the FEDERAL REGISTER of August 4, 1998 (63 FR 41575), were incorrect. Table 2 of this document contains the correct estimates.

The burdens are explained as follows:

1. Reporting

a. *Requests for accreditation*: Under the agency's Third-Party Review Pilot Program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties*: In 18 months under the Third-Party Review Pilot Program, FDA received only 22 510(k)'s that were requested and were eligible for review by third parties. Because the new program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)'s submitted for third-party review will increase. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)'s for third-party review. The agency estimates that each third-party reviewer will require approximately 10 annual hours to maintain records of their reviews and reports.

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29108 Filed 10–29–98; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Surveys to Assess the Outcomes of Curricular Changes at Eight Medical Schools—NEW

In July, 1998, eight medical schools were awarded federal funding under the Undergraduate Medical Education Program for the Twenty-first Century (UME–21) initiative to develop and implement curricular change during the clinical years. This project aims to bring about change in the clinical phase of medical education so that medical students are better prepared for residency training and practice. The selected schools must institute specific changes in their clinical education programs, including the addition of content related to clinical practice in a managed care environment and the introduction of primary care based clinical experiences that cut across the generalist disciplines. UME–21 is administered by the Bureau of Health Professions of the Health Resources and Services Administration. The surveys are designed to: (1) Obtain the opinions of graduating seniors regarding their education in selected topics important for practice in the changing health care environment, and (2) determine whether the physicians who supervise the graduatesduring their first year of residency believe that these graduates possess appropriate knowledge, skills, and attitudes.

The surveys are being conducted as part of a broader evaluation of the overall UME–21 initiative. The study population of students will consist of 2,400 seniors at the eight medical schools, evenly distributed between the graduating classes of 1999 and 2000. The study population of residency program directors will consist of approximately 1,200 physicians in residency programs throughout the country determined by the residency locations of the graduating seniors in each year.

The estimated respondent burden is as follows:

Respondent	Number of respondents	Responses per respondent	Hours per response (minutes)	Total Burden hours
Students	2,400	1	7	280
Program Directors	1,200	2	7	280