information, FDA is revising the scope to address only the reporting and recordkeeping requirements by non-electronic means as described in this document and set forth under § 807.31 for '' Additional Listing Information.'' To reflect the revised scope of this collection of information, FDA has modified the title.

Under § 807.31(a) through (d), each owner or operator is required to maintain an historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements, under § 807.31(e), the owner or operator must be prepared to submit to FDA copies of : (1) All device labeling, (2) all device labeling and representative advertising, or (3) only representative package inserts, depending upon whether the device is subject to the regulatory controls under Sections 514 or 515 of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d and 360e, respectively), or restrictions imposed by 21 CFR 801.109 or otherwise by section 520(e) of the act.

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution in order to effectively allocate FDA's field resources for these inspections, and (3) the class of the device that determines the frequency of inspection. As a result, when complications occur with a particular device or component, all manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, e.g., establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

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 of Response	Total Annual Responses	Hours per Response	Total Hours
807.31(e)	200	1	200	.50	100

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
807.31(a) through (d)	16,200	4	64,800	.50	32,400

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

The annual respondent reporting burden for device establishment registrations and listing is estimated to be 100 hours and the annual respondent recordkeeping burden is estimated to be 32,400 hours. The estimates cited in tables 1 and 2 of this documet are based primarily on the annual FDA accomplishment report, which includes actual FDA registration and listing data derived for fiscal year (FY) 2006. These estimates are also based on FDA estimates of FY 2006 data from current systems and conversations with industry and trade association representatives. FDA anticipates reviewing annually, 200 historical files.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

Dated: January 30, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2079 Filed 2–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review: Comment Request Questionnaire Cognitive Interview and Pretesting (ARP/DCCPS/NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 26, 2007 (Vol. 72, No. 226, p. 65969) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Questionnaire Cognitive Interview and Pretesting. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the data collection is to conduct cognitive interviews, focus groups, Pilot household interviews, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common evaluation method is the cognitive interview, in which a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews. When possible, cognitive interviews are conducted in the survey's intended

mode of administration. Cognitive interviewing provides useful information on questionnaire performance at minimal cost and respondent burden. Similar methodology has been adopted by other federal agencies, as well as by academic and commercial survey organizations. There are no costs to respondents other than their time. *Frequency of Response:* Once. *Affected Public:* Individuals or households.

Type of respondents	Project	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated annual burden hours requested
Questionnaire Development Volunteers.	(1) Survey questionnaire development.	200	1	1.25 (75 minutes)	250.0
General Volunteers	(2) Research on the cognitive aspects of survey methodology.	100	1	1.25 (75 minutes)	125.0
Computer User Volunteers	(3) Research on computer-user interface design.	100	1	1.25 (75 minutes)	125.0
Household Interview Volunteers	(4) Pilot Household interviews	200	1	0.5 (30 minutes)	100.0
Total		600			600.0

The estimated total annual burden hours requested is 600. There are no annualized costs to respondents. The annualized costs to the Federal Government are estimated at $264,000 and include cost of NCI staff to plan, conduct, and analyze outcomes of questionnaire development, $50 payment of pretest participants, contracting for pretesting activities and research, travel costs, and additional materials needed to conduct and recruit participants for the research. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Gordon Willis, PhD., Cognitive Psychologist, Applied Research Program, DCCPS, NCI/NIH, 6130 Executive Blvd., MSC 7344, EPN 4005, Bethesda, MD 20892 or call non-toll-free number 301–594–6652 or e-mail your request, including your address to: *willis@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 28, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E8–2029 Filed 2–4–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel MRI Imaging.

Date: March 5, 2008.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ruixia Zhou, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, (301) 496–4773, *zhour@mail.nih.gov.*

Dated: January 29, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08–481 Filed 2–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–129, Revision of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form I–129, Petition for Nonimmigrant Worker; OMB Control Number 1615–0009.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of