

devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been refused certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the

disposal of a batch of certified or certification-rejected color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for

certification analysis unrepresentative of the batch. FDA checks storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80.21	32	174	5,568	0.20	1,114
80.22	32	174	5,568	0.05	278
TOTAL				0.25	1,392

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
80.39	32	174	5,568	0.25	1,392
TOTAL					1,392

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

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 2,784 hours. The estimated reporting burden for this information collection is 1,392 hours and the estimated recordkeeping burden for this information collection is 1,392 hours. From FY 2004 to FY 2006, FDA processed an average of 5,568 responses (requests for certification of batches of color additives) per year. There were 32 different respondents, corresponding to an average of approximately 174 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.25 hour per response is required for reporting (preparing certification requests and accompanying sample labels) and an average of 0.25 hour per response is required for recordkeeping.

On February 13, 2006, FDA introduced a Web-based Color Certification information system. The system was fully operational for FY 2007. This system allows certifiers to

request color certification on-line, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing certifiers to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA expects future reductions in the hour burdens for reporting and recordkeeping from use of the Web-based system.

Dated: July 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Panels or Committees and Request for Nonvoting Industry Representatives on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) and certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health notify FDA in

writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by August 23, 2007, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by August 23, 2007.

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 7520 Standish Pl. (MPN1), Rockville, MD 20855, 240-276-8938, e-mail: kathleen.walker@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The agency intends to add nonvoting industry representatives to its advisory committee identified below:

I. CDRH—Various Committees and Panels

A. National Mammography Quality Assurance Advisory Committee (NMQAAC)

The Mammography Quality Standards Reauthorization Act of 2004 (Public Law 108-365) requires the addition of at

least two industry representatives with expertise in mammography equipment to the NMQAAC.

B. Medical Devices Advisory Committee

Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.

II. CDRH—Committee and Panel Functions

FDA is requesting nominations for nonvoting members representing industry interests for the following vacancies listed in table 1 of this document.

TABLE 1.

Committee Name or Panel	Approximate Date Needed
NMQAAC—The functions of the NMQAAC are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities, (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program, (3) developing regulations with respect to sanctions, (4) developing procedures for monitoring compliance with standards, (5) establishing a mechanism to investigate consumer complaints, (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities, (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas, (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999, and (9) determining the costs and benefits of compliance with these requirements	February 1, 2008
Certain Panel of the Medical Devices Advisory Committee—The medical device panels perform the following functions: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation, (2) advise the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of these devices into one of three regulatory categories, (3) advise on any possible risks to health associated with the use of devices, (4) advise on formulation of product development protocols, (5) review premarket approval applications for medical devices, (6) review guidelines and guidance documents, (7) recommend exemption to certain devices from the application of portions of the act, (8) advise on the necessity to ban a device, (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices, and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. Clinical Chemistry and Clinical Toxicology Devices Panel Gastroenterology and Urology Devices Panel Medical Devices Dispute Resolution Panel Microbiology Devices Panel Molecular and Clinical Genetics Devices Panel Orthopaedic and Rehabilitation Devices Panel Radiological Devices Panel	March 1, 2008 January 1, 2008 October 1, 2008 March 1, 2008 June 1, 2008 September 1, 2008 February 1, 2008

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the contact person (see **FOR FURTHER**

INFORMATION CONTACT) within 30 days of publication of this notice. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with

their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry

interests for a particular committee or device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

IV. Qualifications

A. NMQAAC

Persons nominated for membership as an industry representative on the NMQAAC must meet the following criteria: (1) Demonstrate expertise in mammography equipment, and (2) be able to discuss equipment specifications and quality control procedures affecting mammography equipment. The industry representative must be able to represent the industry perspective on issues and actions before the advisory committee, serve as liaison between the committee and interested industry parties, and facilitate dialogue with the advisory committee on mammography equipment issues.

B. Medical Devices Advisory Committee

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

V. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages, nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the food production and manufacturing industry; the dietary supplement manufacturing industry;

and the agricultural biotechnology manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: July 16, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7-14206 Filed 7-23-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; Revision of OMB; No. 0925-0001/exp. 09/30/07, "Research and Research Training Grant Applications and Related Forms"

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Research and Research Training Grant Applications and Related Forms. Type of Information Collection Request: Revision, OMB 0925-0001, Expiration Date 9/30/07. *Form Numbers:* PHS 398, 2590, 2271, 3734 and HHS 568. *Need and Use of Information Collection:* The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. *Frequency of response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. *The annual reporting burden is as follows:* *Estimated Number of Respondents:* 158,820; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 15.8; and *Estimated Total Annual Burden Hours Requested:* 2,517,466. The estimated annualized cost to respondents is \$88,058,547.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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) 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) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number 301-435-0941, or e-mail your request, including your address to: curriem@od.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: July 16, 2007.

Mikia Currie,

OPERA, Office of Extramural Research, National Institutes of Health.

[FR Doc. E7-14214 Filed 7-23-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent