

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	6	1	6	48	288

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

Under section 409(a) of the act, the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the act, (2) it conforms to the terms of a regulation prescribing its use, or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would

result from the proposed use. FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 3, 2004, from 8:30 a.m. to 5 p.m.

Location: Gaithersburg Marriott, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512526. Please call the Information

Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a computer aided detection device that identifies nodules in CT (computerized tomography) images of the lung. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material will be posted on February 2, 2004.

Procedure: On February 3, 2004, from 9 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 27, 2004. On February 3, 2004, oral presentations from the public will be scheduled between approximately 9:20 a.m. and 9:50 a.m., and for an additional 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 27, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 3, 2004, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management

Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Radiological Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Radiological Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 5, 2004.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04-1379 Filed 1-22-04; 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, Public Law 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) 443-1129.

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: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915-0204)—Extension

The Health Education Assistance (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan

associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, make new refinanced HEAL loans which are insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program refinances previous HEAL loans, monitors the Federal liability, and assists in default prevention activities. The HEAL borrower, the borrower's physician, and the holder of the loan completes the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim.

The estimate of burden for the Physician's Certification form is as follows:

Type of respondent	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
Borrower ¹	117	1	117	5	10
Physician	117	1	117	30	59
Loan Holder	20	5.85	117	10	20
Total	254	351	89

¹ Includes 2 categories of borrowers requesting disability waivers: (1) whose loans have previously defaulted, and (2) whose loans have not defaulted.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 15, 2004.
Tina M. Cheatham,
Acting Director, Division of Policy Review and Coordination.
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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