TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	4,500	1	4,500	0.02	90
Interview	1,060	1	1,060	2.4	2,544
Total					2,699

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

These estimates are based on FDA's experience with previous consumer studies. Prior to the administration of the experiment, the agency plans to conduct a pretest of the final questionnaires to minimize potential problems in administration of the interviews. The pretest will be conducted in up to three waves, each with nine participants. The agency will use a screener to select an eligible adult in each household to participate in the study. Each pretest, as well as actual interview, is expected to last no more than a total of 2.4 hours (10 minutes for the telephone interview, 15 minutes for the CASAI, and 2 hours for traveling time to and from the CASAI location).

The anticipated sample size per condition is approximately 120. This sample size is expected to identify small to medium effects with a power of 0.8 and at the .05 significance level.

Dated: December 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–27119 Filed 12–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0478]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.'' This guidance document describes a means by which an implantable radiofrequency transponder system for patient identification and health information may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the implantable radiofrequency transponder system for patient identification and health information into class II (special controls). This guidance document is immediately in effect as the special control for the device, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Gail Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the implantable radiofrequency transponder system for patient identification and health information into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the Implantable Radiofrequency Transponder System for Patient Identification and Health Information device.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on special controls for the implantable radiofrequency transponder system for patient identification and health information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information'' by FAX, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1541) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The quality system regulation provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0073. The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–27078 Filed 12–9–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Loan Repayment; Proposed Collection; Comment Request; National Institutes of Health Loan Repayment Programs

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 Loan Repayment, 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: National Institutes of Health Loan Repayment Programs. *Type of Information Collection Request:* Revision of currently approved collection (OMB No. 0925–0361, expiration date 12/31/04). Form Numbers: NIH 2674–1, NIH 2674–2, NIH 2674–3, NIH 2674–4, NIH 2674–5, NIH 2674–6, NIH 2674–7, NIH 2674–8, NIH 2674–9, NIH 2674–10, NIH 2674–11, NIH 2674–12, and NIH 2674–14. *Need and Use of Information Collection:* The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., D.D.S., D.M.D., D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or biobehavioral research in NIH intramural laboratories or as extramural grantees for a minimum of 2 years (3 years for the General Research Loan Repayment Program) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS–LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288–1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP) is authorized by Section 487E (42 U.S.C. 288–5); the General Research Loan Repayment Program (GR–LRP) is authorized by Section 487C (42 U.S.C. 288–3); the Loan Repayment Program Regarding Clinical Researchers (LRP–CR) is authorized by Section 487F (42 U.S.C. 288–5a); the Pediatric Research Loan Repayment Program (PR–LRP) is authorized by Section 487F (42 U.S.C. 288–6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR–LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288–5); the Contraception and Infertility Research LRP (CIR–LRP) is authorized by Section 487B (42 U.S.C. 288–2); and the Health Disparities Research Loan Repayment Program (HD–LRP) is authorized by Section 485G (42 U.S.C. 287c–33).

The Loan Repayment Programs provide for the repayment of up to $35,000 a year of the principal and interest of the educational loan debt of qualified health professionals who agree to conduct qualifying research for each year of obligated service. The information proposed for collection will be used to determine an applicant's eligibility for participation in the program.

Frequency of Response: Initial application and annual renewal application. *Affected Public:* Applicants, financial institutions, research institutions, recommenders. *Type of Respondents:* Physicians, other scientific or medical personnel, and organizational officials. The annual reporting burden is as follows: