(FDA Form 483), this draft guidance recommends that the applicant do the following: (1) Describe their investigation of the cause or source of the problem; and (2) explain their decision to change the device design, labeling, or manufacturing process by describing how the actions taken have corrected the problem and mitigated the harm.

This draft guidance also recommends including a discussion of how the results and conclusions in clinical investigations or nonclinical laboratory studies or reports in scientific literature could impact the known safety and effectiveness profile of the device. If changes to the device or its labeling are based on clinical investigations or nonclinical laboratory studies or reports in scientific literature, this draft guidance recommends informing FDA of a plan for submitting a PMA Supplement or 30-day notice for these changes; or in the alternative, explaining why such a submission is not appropriate.

To help FDA assess the public health impact of the information provided in annual reports, this draft guidance also asks applicants to provide data about the number of devices shipped or sold during the reporting period. For device implants, data regarding the number of devices actually implanted should be provided, if it is available.

Finally, this draft guidance suggests that a redacted copy of the annual report may be provided in order to be publicly posted on FDA's Web site.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 814.82(a)(7) and 814.84(b) have been approved under OMB Control No. 0910–0231.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Information Collection Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report Cover Letter	434	1	434	0.5	217
Rationale for Changes	434	1	434	3	1,302
Summary of Risk Analysis	434	1	434	4	1,736
Evaluation of Clinical Investigations, Non-Clinical Laboratory Studies, or Scientific Literature	434	1	434	7	3,038
Information on Devices Shipped, Sold, or Implanted	434	1	434	5	2,170
Redacted Copy of Annual Report	434	1	434	4	1,736
Total	434	1	434	29.5	10,199

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

The industry-wide burden estimate is based on an FDA actual average fiscal year (FY) annual rate of receipt of 434 annual reports, using FY 2003 through 2005 data. The burden data for annual reports is based on FDA estimates.

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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 17, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–17908 Filed 10–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Cancellation: Change of Meeting Date

AGENCY: Health Resources and Services Administration; HHS.

ACTION: Meeting notice: cancellation and change of meeting date.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** of September 22, 2006, regarding a meeting date for the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. The meeting scheduled for November 2–3, 2006, has been cancelled.

Correction

In the **Federal Register** of September 22, 2006, in FR Doc. 06–8018, on page 55494, correct the ''Dates and Times'' section to read:

Dates and Times: December 18, 2006, 9 a.m. to 5 p.m., December 19, 2006, 8:30 a.m. to 3 p.m.

Place: Hilton Washington Hotel, Monroe Room, 1919 Connecticut Avenue, NW., Washington, DC 20009.

Dated: October 20, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–17931 Filed 10–25–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Health Information National Trends Survey 2007 (HINTS 2007)

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 National Cancer Institute (NCI), 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: Health Information National Trends Survey 2007 (HINTS 2007).

Type of Information Collection Request: New.

Need and Use of Information Collection: Building on the first two rounds of HINTS data collection, HINTS 2007 will continue to provide NCI with a comprehensive assessment of the American public's current access to, and use of, information about cancer, including cancer prevention, early detection, diagnosis, treatment, and prognosis. The content of the survey will focus on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained. HINTS is intended to be the foundation of NCI's effort to build on the opportunities presented by a national shift in communication context, and by so doing, improve the nation's ability to reduce the national cancer burden. Data will be used (1) To understand individuals sources of and access to cancer-related information; (2) to measure progress in improving cancer knowledge and communication to the general public; (3) to develop appropriate messages for the public about cancer prevention, detection, diagnosis, treatment, and survivorship; and (4) to identify research gaps and guide decisions about NCI's research efforts in health promotion and health communication.

Frequency of Response: One time.

Affected Public: Individuals.

Type of Respondents: U.S. Adults.

The annual reporting burden is as follows:

Estimated Number of Respondents: 10,599.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: .33.

Estimated Total Annual Burden Hours Requested: 3,576.

The annualized cost to respondents is estimated at: $35,760. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Frequency of response	Average hours per response	Annual hour burden
Pilot RDD Screener	250	1	.0833	21
Pilot RDD Interview*	150	1	.4167	63
Pilot Mail Survey	150	1	.3333	50
RDD Screener	5,833	1	.0833	486
RDD Interview*	3,500	1	.4167	1,458
Mail Survey	3,660	1	.3333	1,219
Telephone Screener for Followup of Mail	956	1	.0833	80
Telephone Interview for Follow-up of Mail*	478	1	.4167	199
Totals	.....	.....	.....	3,576

* Pilot survey and HINTS 2007 RDD interview respondents are a subset of the RDD screener respondents. Similarly, the telephone interview respondents in the followup of mail nonrespondents are a subset of the telephone screener respondents in the followup of mail nonrespondents. N = 10,849.

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 Bradford W. Hesse, Ph.D., Project Officer, National Cancer Institute, NIH, EPN 4068, 6130 Executive Boulevard MSC 7365, Bethesda, Maryland 20892–7365, or call non-toll-free number 301–594–9904, or FAX your request to 301–480–2198, or E-mail your request, including your address, to *hesseb@mail.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: October 18, 2006.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E6–17964 Filed 10–25–06; 8:45 am]

BILLING CODE 4101–01–P

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 applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the