(FDA Form 483), this draft guidance recommends that the applicant do the following: (1) Describe their investigation of the cause or source of the problem; and (2) explain their decision to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This draft guidance also recommends including a discussion of how the results and conclusions in clinical investigations or nonclinical laboratory studies or reports in scientific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are based on clinical investigations or nonclinical laboratory studies or reports in scientific literature, this draft guidance recommends informing FDA of a plan for submitting a PMA Supplement or 30-day notice for these changes; or in the alternative, explaining why such a submission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To help FDA assess the public health impact of the information provided in annual reports, this draft guidance also asks applicants to provide data about the number of devices shipped or sold during the reporting period.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Finally, this draft guidance suggests that a redacted copy of the annual report may be provided in order to be publicly posted on FDA's Web site.

This draft guidance also refers to previously approved collections of information found in FDA regulations.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