

ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
CDI Surveillance Case Report Form—Partial .....	10	438	15/60
CDI Surveillance Health Interview .....	10	50	45/60

Dated: March 9, 2011.  
**Carol Walker,**  
*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*  
 [FR Doc. 2011-5919 Filed 3-14-11; 8:45 am]  
**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Withdrawal of Publication**

This is to serve notice that the following **Federal Register** notice published on March 1, 2011, page 11250, is being rescinded:

**Submission for OMB Review: Comment Request**

*Title:* Child Care and Development Fund Tribal Plan Preprint—ACF-118-A.

*OMB No.:* 0970-0198.

The original notice published on February 9, 2011, pages 7218-7219 is still in effect.

Dated: March 9, 2011.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 2011-5845 Filed 3-14-11; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0554]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by April 14, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0359. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, *Daniel.Gittleson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Devices; Reports of Corrections and Removals—(OMB Control Number 0910-0359)—(Extension)**

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 301) (Pub. L. 105-115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed

devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

Respondents to this collection of information are manufacturers and importers of medical devices. FDA reviewed reports of device corrections and removals submitted to the Agency for the previous 3 years as part of responding to the current request for approval of the information collection requirements for §§ 806.10 and 806.20. This information was obtained through the Agency's voluntary recall provisions (*i.e.*, 21 CFR part 7). The specific information requested was the total number of class I, II, and III recalls for the last 3 years. This information was obtained from the Agency's Recall Enterprise System—a database of all recalls submitted to the Agency.

This information is relevant since a § 806.10 report is required for all class I and II recalls. Although class III recalls are not required to be submitted to FDA (by § 806.10), a record must be kept in the firm's § 806.20 file. Therefore, the number of class I and II recalls can be used to estimate the maximum number of reports that are required to be submitted under § 806.10. Also, the recordkeeping burden can be estimated based upon the number of class III recalls, which are not required to be reported, but must be retained in a § 806.20 file.

FDA has determined that estimates of the reporting burden for § 806.10 should be revised to reflect a projected 7.3 percent increase (from the last PRA numbers) in reports submitted to FDA as class I and II. FDA also estimates the recordkeeping burden in § 806.20 should be revised to reflect a reduction of 6.8 percent (from the last PRA numbers) in records filed and maintained under § 806.20. The estimates of time needed to collect part 806 information have not changed.

In the **Federal Register** of November 23, 2010 (75 FR 71446), FDA published a 60-day notice requesting public comment on the proposed collection of