

Examples of topical areas include infant, child, adolescent, parent, and family health, well-being, and knowledge, attitude, and behaviors; children with special health care needs (CSHCN); functioning; life course and social determinants of health; developmental delays and disabilities; acute and chronic conditions; immunizations; access to and use of health care; program participation; adoption; and changes in health insurance coverage and experiences.

Users of SLAITS data include, but are not limited to, Congressional offices, Federal agencies, state and local

governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, advocates, and health planners, to evaluate content and/or programs. SLAITS data continue to be heavily used by Federal and state Maternal and Child Health Bureau Directors to evaluate programs and service needs. Several SLAITS modules provided data for multiple Congressionally-mandated reports on healthcare disparities and quality; at least one report to Congress on health insurance coverage among children; and

reports of the National Academy of Sciences. Within DHHS, the Office of the Assistant Secretary for Planning and Evaluation and the Administration for Children and Families used SLAITS to collect data for the first nationally representative survey of adoptive families across adoption types for children with and without special health care needs, and to assess their post-adoption service use and unmet needs.

There is no cost to respondents other than their time to participate. The total estimated annualized burden hours are 194,675.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Household screening	1,800,000	1	2/60
Household interview	306,000	1	25/60
Pilot work, pre-testing, and planning activities	12,300	1	35/60

Dated: March 9, 2011.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011-5920 Filed 3-14-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day 11-10GP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Clostridium difficile Infection (CDI) Surveillance—New—National Center for Emerging and Zoonotic Infectious Diseases, (NCEZID), Centers for Disease Control and Prevention, (CDC).

Background and Brief Description

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments of the impact of CDI in the United States. *C. difficile* is an anaerobic, spore-forming, gram positive bacillus that produces two pathogenic toxins: A and B. CDI ranges in severity from mild diarrhea to fulminant colitis and death. Transmission of *C. difficile* occurs primarily in healthcare facilities, where environmental contamination by *C. difficile* spores and exposure to antimicrobial drugs are common. No longer limited to healthcare environments, community-associated CDI is the focus of increasing attention. Recently, several cases of serious CDI have been reported in what have been considered low-risk populations, including healthy persons living in the community and peri-partum women.

The surveillance population will consist of persons residing in the

catchment area of the participating Emerging Infections Program (EIP) sites. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing positive for *C. difficile* toxin and abstract data on cases using a standardized case report form. For a subset of cases (e.g., community-associated *C. difficile* cases) sites will administer a health interview. Remnant stool specimens from cases testing positive for *C. difficile* toxin will be submitted to reference laboratories for culturing, and isolates will be sent to CDC for confirmation and molecular typing. Outcomes of this surveillance project will include the population-based incidence of community- and healthcare-associated CDI, and a description of the molecular characteristics of *C. difficile* strains and the epidemiology of this infection among the population under surveillance.

There is no cost to respondents to participate in this program. The total annualized burden for this data collection is 5,840 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
CDI Surveillance Case Report Form—Complete	10	437	1

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]

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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]

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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 oir_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