ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
Parent	Social Isolation/Support	178	1	2/60
Parent	Strengths and Difficulties Questionnaire (SDQ)	190	2	3/60
Parent	Vanderbilt Parent Rating Scale	190	2	10/60
Child	Brief Sensation Seeking Scale	190	1	1/60
Child	Conflict in Adolescent Dating Relationships	153	1	10/60
Child	Health Risk Behavior Survey (Middle School) 11–13 years	37	1	15/60
Child	Health Risk Behavior Survey (High School) 14+ years	153	1	25/60
Child	MARSH—Self Description Questionnaire v I, 7–12 years	15	1	5/60
Child	MARSH—Self Description Questionnaire v II, 13–15 years	90	1	7/60
Child	MARSH—Self Description Questionnaire v III 16+ years	85	1	9/60
Child	Social Inventory (High School) 14+ years	153	1	10/60
Child	Olweus Bullying Questionnaire (High School) 14+ years	153	1	7/60
Child	Pediatric Quality of Life Child (8–12)	15	1	5/60
Child	Pediatric Quality of Life Teen (13+)	175	1	5/60
Child	Youth Demographic Survey, 16+ years	85	1	5/60
Teacher	Teacher Survey	949	1	10/60

Dated: February 1, 2010.

Maryam I. Daneshvar,

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

[FR Doc. 2010–2600 Filed 2–5–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0489]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

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 March 10, 2010.

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 0910–0598. 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 (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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.

Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications—21 CFR Section 493 (OMB Control Number 0910–0598)—Extension

Congress passed the Clinical Laboratory Improvements Amendment (CLIA) (Public Law 100–578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver (42 U.S.C. 263a(c)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" under CLIA (69 FR 22849, April 27, 2004). This guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it "simple"; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results. Only new information collections not already approved are included in the estimate in the following table. Quick reference instructions are a short version of the instructions that are written in simple language and that can be posted.

The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting. Based on previous years experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and

maintaining the record for a total of 112,000 hours. The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000). This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437.

In the **Federal Register** of October 20, 2009 (74 FR 53750), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
493.15(a) and (b)	40	1	40	780	31,200	$50,200

[1] There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Operating and Maintenance Costs
493.15(a) and (b)	40	1	40	2,800	112,000	$16,000

[1] There are no capital costs associated with this collection of information.

Dated: January 25, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–2598 Filed 2–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Lost People Finder System

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 Library of Medicine (NLM), 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: Lost People Finder System; *Type of Information Collection Request:* Extension of currently approved collection [OMB No. 0925–0612, expiration date 07/31/2010], *Form Number:* NA; *Need and Use of Information Collection:* The National Library of Medicine (NLM) proposes the continuation of a voluntary collection of data to assist in the reunification of family members and loved ones who are separated during a disaster. Reunification is important to both the emotional well-being of people injured during a disaster and to their medical care. Family members often provide important health information to care providers who are treating the injured (*e.g.*, providing medical history or information about allergies) and they may provide longer-term care for those released from emergency care. NLM proposes this data collection as part of its mission to develop and coordinate communication technologies to improve the delivery of health services. The data collection is authorized pursuant to sections 301, 307, 465 and 478A of the Public Health Service Act [42 U.S.C. 241, 242l, 286 and 286d]. NLM is a member of the Bethesda Hospitals' Emergency Preparedness Partnership (BHEPP), which was established in 2004 to improve community disaster preparedness and response among hospitals in Bethesda, Maryland that would likely be called upon to absorb mass casualties in a major disaster in the National Capital Region. BHEPP hospitals include the National Naval Medical Center (NNMC), the National Institutes of Health Clinical Center (NIH CC), and Suburban Hospital/Johns Hopkins Medicine. NLM, with its expertise in communications, information management, and medical informatics joined BHEPP to coordinate the R&D program, one element of which is development of a lost person finder to assist in family reunification after a disaster. NLM's Lost People Finder System would collect information, on a voluntary basis, about people who are missing and who are found (recovered) during a disaster. Information on recovered individuals would be gathered voluntarily from medical and relief personnel who either use a specialized application developed by NLM for the iPhone or submit information to NLM by e-mail via computer or cell phone. The iPhone application enables submission of photographs and descriptive information about recovered victims in a structured format, *e.g.*, name (if available), age category, gender, general status (healthy, injured), location. Information about missing persons would be submitted by members of the public who are seeking family members, friends, and other loved ones. An interactive Web-based system offers the public a tool for searching for people who have been found (*e.g.*, recovered by medical staff and other relief workers) and for voluntarily posting information about people who are still missing. In addition, the system would collect information on a regular basis from other publicly available systems for that are used for reunification during a disaster for information (*e.g.*, the Google Person Finder system that was deployed during the 2010 earthquakes in Haiti). In addition, information submitted directly to NLM's Lost People Finder System would be transferred to other systems that are endorsed by U.S. government agencies to ensure that users of such systems can search the complete set of available information for their family members and loved ones and to ensure that use of the NLM system in no way interrupts or distracts from the