ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Director of health information management (DHIM) or Health information technology (DHIT).	Induction (including initial facility questionnaire).	167	1	4	668
DHIM or DHIT	Post induction annual facility questionnaire.	500	2	1	1,000
DHIM or DHIT	transmit UB–04	500	4	1	2,000
Acute Coronary Syndrome Pretest:					
Hospital CEO/CFO	Presentation at hospital	11	1	1	11
DHIM or DHIT	Pulling medical records for abstraction.	11	1	30/60	6
Total					3,852

Dated: August 4, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–19704 Filed 8–9–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-10–10CV]

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

Early Aberration Reporting System (EARS) Registration Module—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)(proposed), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

To support two of CDC's main priority areas: (1) Improving CDC's support for state and local health departments, and (2) strengthening surveillance and epidemiology, CDC is requesting approval from the Office of Management and Budget (OMB) to improve the Early Aberration Reporting System (EARS) by collecting data from individuals who request a download of EARS from the CDC Web site.

The Early Aberration Reporting System, developed within the Division of Bioterrorism Preparedness and Response, is a Web-enabled tool that analyzes public health surveillance data using methods that detect abnormal trends that could possibly indicate an outbreak of infectious disease. The local public health professionals manage the entire tool and can implement the defaults or can adjust the tool in order to meet their local needs. The goal of this process is to assist public health professionals in the early identification of outbreaks of disease as well as bioterrorism events. EARS is used to assess whether the current number of reported cases of an event is higher than usual.

The term syndromic surveillance is used to describe surveillance that uses health-related data that precede diagnosis and that signals a sufficient probability of a case or an outbreak of infectious disease to warrant further public health response. Syndromic surveillance systems are used by state, local, national and international health departments to monitor syndrome-based (*e.g.,* case information collected in emergency departments (EDs) and diagnostic data sources for early detection of outbreaks and other public health events). More recently these systems are used during public health responses to provide more rapid near real-time situational awareness regarding the health status of the target population. EARS were the first software platform to support local syndromic surveillance systems. EARS has been designed and used to monitor syndromic data from emergency departments, 911 calls, physician office data, school and business absenteeism, over-the-counter drug sales, laboratory testing and results data and reportable disease surveillance systems. In the past several years, EARS systems have been integral in the local public health surveillance arsenal. EARS has been used at events such as the Beijing Summer Olympics; multiple Superbowls (football) and World Series (baseball); the political conventions of both major US political parties; and the Presidential Inauguration (2009).

Today, EARS is a highly successful and sustainable system and has over 200 users at the federal, state, local, and international levels. These users include international Ministries of Health and domestic state and local public health departments. Additionally, EARS detection methods have been integrated in well-known surveillance platforms such as BioSense at CDC, ESSENSE at Johns Hopkins, NAMRD at US Department of Defense, and Emergint at Northrop Grumman.

EARS is widely-accepted and easily sustainable due to its being free to all end users, the capacity to use multiple forms of data, flexibility and user-driven design and maintenance. EARS is a service provided by CDC as share-ware and is available by download at no cost from the CDC Web site *http://www.bt.cdc.gov/surveillance/EARS.*

In an effort to continue to improve and enhance EARS, the collection of registration information is needed to track users and organizations to assist in future needs assessments. Requiring the users to register will provide CDC with contact information (*i.e.,* e-mail addresses) to use for broadcast e-mails regarding new releases for upgrades and enhancements; track the number of users, the download frequency, and the type of data that users will monitor with

EARS; and solicit users for feedback for future upgrades and enhancements.

There is no cost to respondents to participate in this program. The total estimated annualized burden for this data collection is 25 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Users	150	1	10/60

Dated: August 4, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–19702 Filed 8–9–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

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 September 9, 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 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Infant Formula Requirements—21 CFR Parts 106 and 107 (OMB Control Number 0910–0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. In a notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1, 2, and 3 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of May 4, 2010 (75 FR 23777), 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]

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the act	5	13	65	10	650
21 CFR 106.120(b)	1	1	1	4	4
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	1	1	1	4	4
Total					682

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