burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Assessment of the Effectiveness of the Center for Disease Control and Prevention's (CDC) Guidelines for Prevention of Surgical Wound Infections—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC..

In the U.S. an estimated 31.8 million surgical procedures are performed each year. Despite advances in infection control practices, surgical technique and antisepsis, and the introduction of antimicrobial prophylaxis, surgical site infections (SSIs) remain a leading cause of healthcare-associated morbidity and mortality. An estimated 2%–5% of surgical procedures done each year are complicated by SSI. In addition, SSIs result in an additional 7.4 days of hospitalization and $400–$2,600 in healthcare costs/infection, resulting in an annual cost of $130–$845 million/year. Since the early 1980's CDC has developed and disseminated guidelines for the prevention of SSIs. However, the degree of practitioner and institutional compliance with the guideline and the impact of the CDC-recommended precautions in preventing SSIs have not been determined. The Institute of Medicine and the Healthcare Infection Control Practices Advisory Committee have strongly advised that systematic guideline evaluation be a standard component of the guideline development process.

The purpose of this project is to assess the effectiveness of CDC Guidelines to Prevent Surgical Site Infection. The objective of this study is to determine knowledge, attitudes, and practices of surgeons regarding the Guidelines.

A mail and Internet survey will be conducted among a representative sample of members of the American College of Surgeons. The survey will ask about surgical practices and opinions related to surgical site infections. Participation in the survey will be voluntary. There is no cost to the respondents other than their time.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/respondent (in hours)	Total burden (in hours)
American College of Surgeons	2134	1	30/60	1067
Total				1067

Dated: May 24, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–14128 Filed 6–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–30–02]

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) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

National Public Health Performance Standards Program Local Public Health System Assessment—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

Since 1998, the CDC National Public Health Performance Standards Program has convened workgroups with the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), the National Association of Local Boards of Health NALBOH), the American Public Health Association (APHA), and the Public Health Foundation (PHF) to develop performance standards for public health systems based on the ten Essential Services of Public Health. In the fall of 2000, CDC conducted field tests with the local public health survey instruments in the States of Hawaii, Minnesota, and Mississippi.

CDC is now proposing to implement a voluntary data collection to assess the capacity of local public health systems to deliver the Essential Public Health Services. Electronic data submission will be the method of choice. If computer technology in local jurisdictions does not support electronic submission, hard-copy survey instruments will be available. Local jurisdictions using hard-copy survey instruments will receive assistance from State or local level field coordinators for web-based data entry.

Local health departments will respond to the survey on behalf of the collective body of representatives from the local public health system. An estimated 33 percent of local health departments will complete the local instrument in year one, 30 percent in year two and 25 percent in year three. The total burden hours are estimated to be 67,200.

Data collection period	Respondents	Responses per respondent	Average burden response (in hrs.)
Year 1 ...	875	1	24
Year 2 ...	1167	1	24
Year 3 ...	875	1	24

Dated: May 29, 2002.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–14127 Filed 6–5–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0055]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by July 8, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280 (OMB Control Number 0910–0188)—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall, by regulation, prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with an FDA approved notice of recall. Section 107.240 requires the recalling firm to: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

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 per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	3	1	3	4,500	13,500
107.240	3	1	3	1,482	4,446
107.250	3	1	3	120	360
107.260	3	1	3	650	650
Total					18,956

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

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice. The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been three recalls in the last 3 years, or one recall annually.

Dated: May 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14169 Filed 6–5–02; 8:45 am]

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